

PASIREOTIDE: REAL WORLD EXPERIENCE

**QUALITY of LIFE
Padua's experience**

Mattia Barbot

U.O.C Endocrinologia Padova, DIMED

Altogether
to Beat
Cushing's
Syndrome

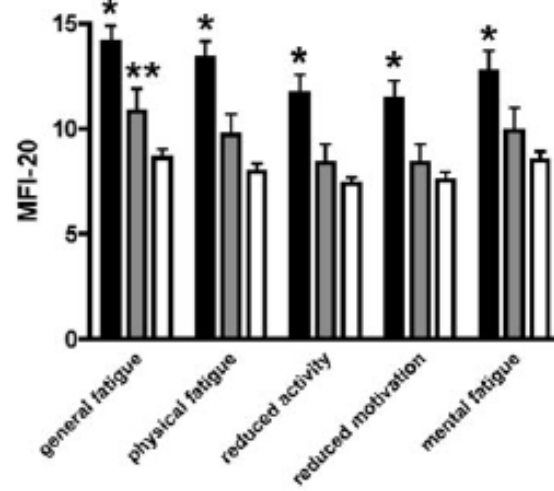
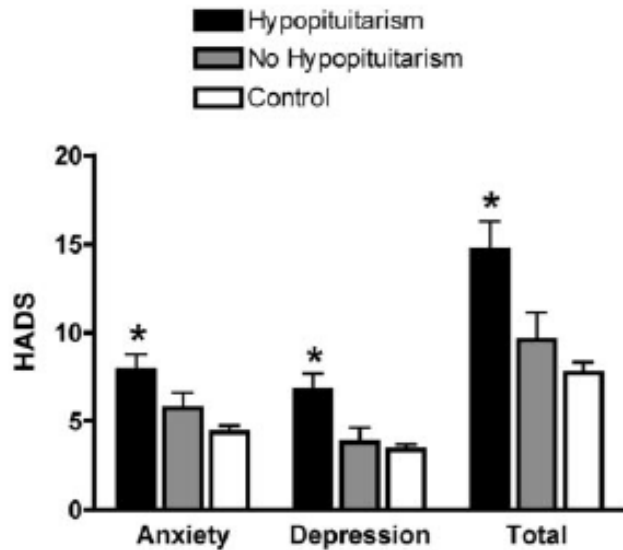


**Viaggio alla
(ri)scoperta
della Sindrome
di Cushing**
Quarta Edizione

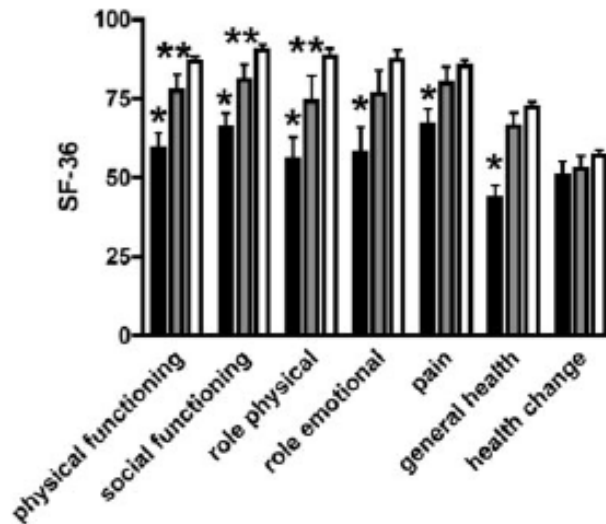
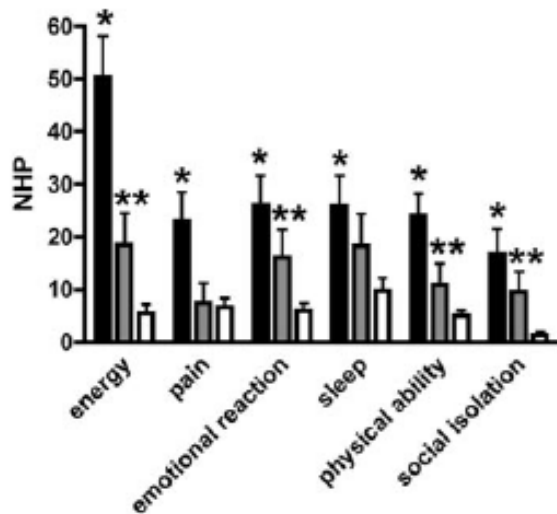
Napoli, 5-7 maggio 2015
Hotel S. Lucia

Quality of Life in Patients after Long-Term Biochemical Cure of Cushing's Disease

M. O. van Aken, A. M. Pereira, N. R. Biermasz, S. W. van Thiel, H. C. Hoftijzer, J. W. A. Smit, F. Roelfsema, S. W. J. Lamberts, and J. A. Romijn

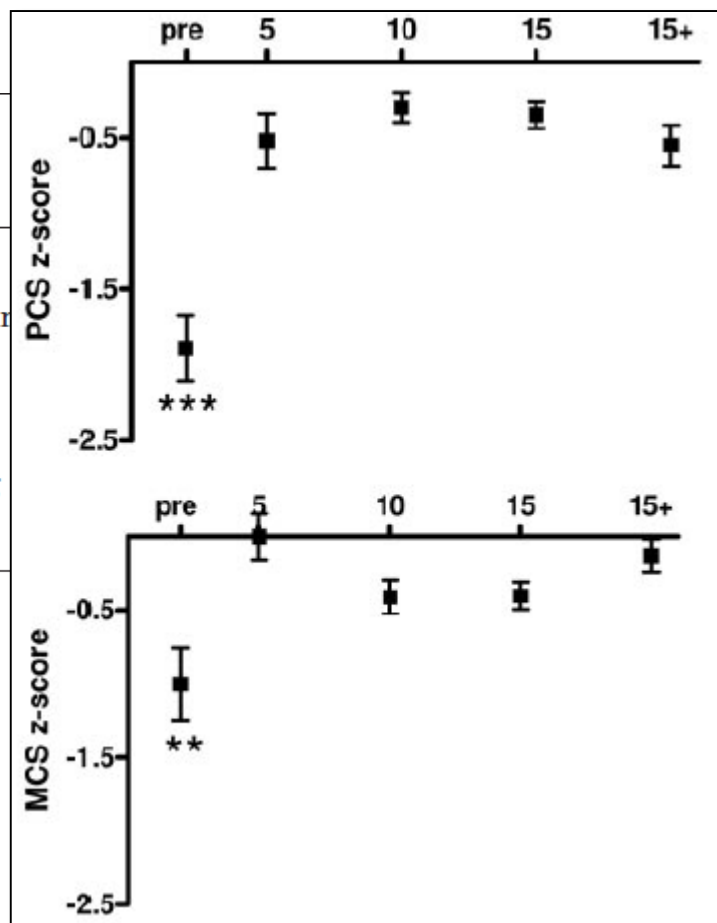


Age, gender and hypotuitarism associated with impaired QoL



Long-Term Impaired Quality of Life in Cushing's Syndrome despite Initial Improvement after Surgical Remission

John R. Lindsay, Tonya Nansel, Smita Baid, Julie Gumowski, and Lynnette K. Nieman



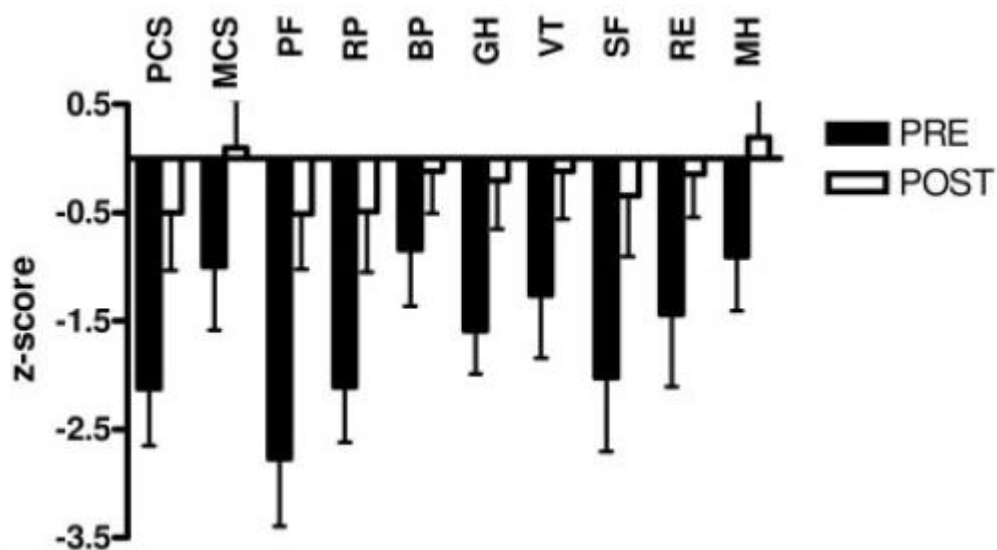
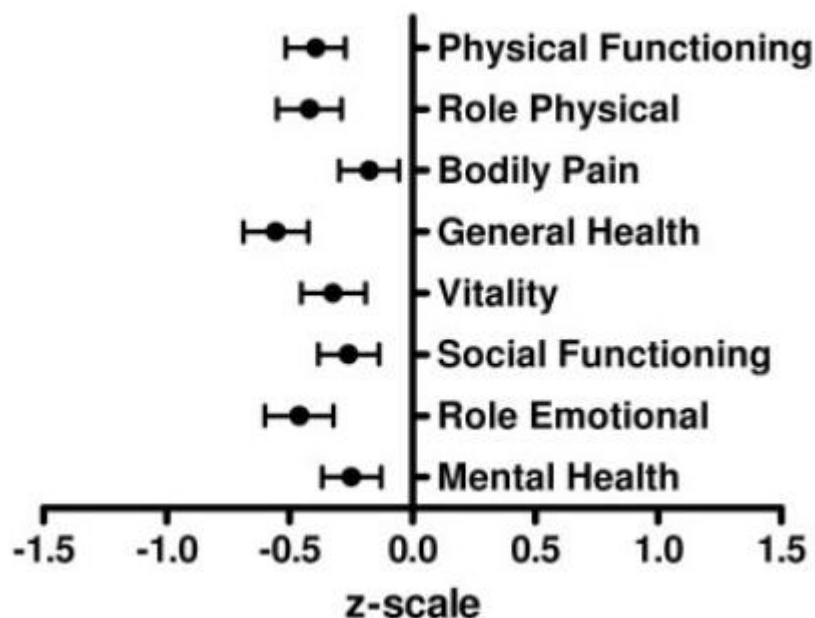
Pre-Rx cross-sectional (n=343)	Pre- vs. post-Rx CD (P value)	Pre-Rx CD vs. cross-sectional post-Rx (P value)	Post-Rx CD vs. cross-sectional post-Rx (P value)
(11.4)	<0.0001	0.002	0.20

Stable but impaired HRQL over time.
 Previous pituitary radiation and current glucocorticoid use had little effect on HRQL outcomes

PCS
 MCS
 Physical functioning
 Role physical
 Bodily pain
 General health
 Vitality
 Social functioning
 Role emotional
 Mental health

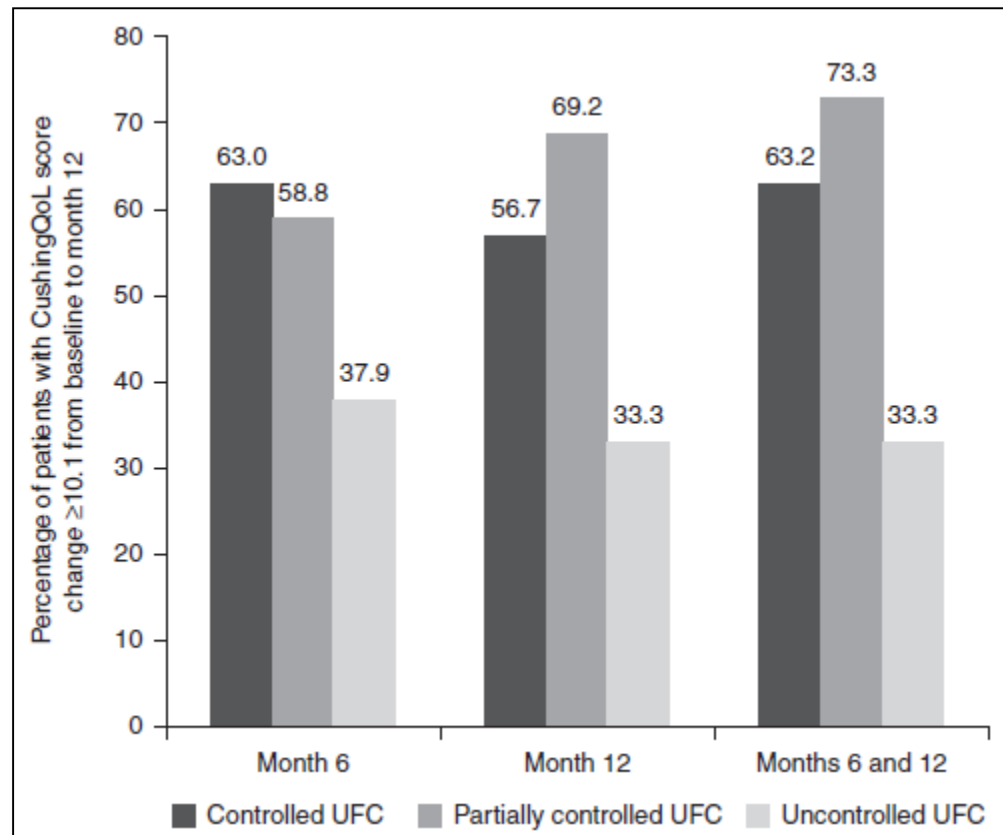
Long-Term Impaired Quality of Life in Cushing's Syndrome despite Initial Improvement after Surgical Remission

John R. Lindsay, Tonya Nansel, Smita Baid, Julie Gumowski, and Lynnette K. Nieman



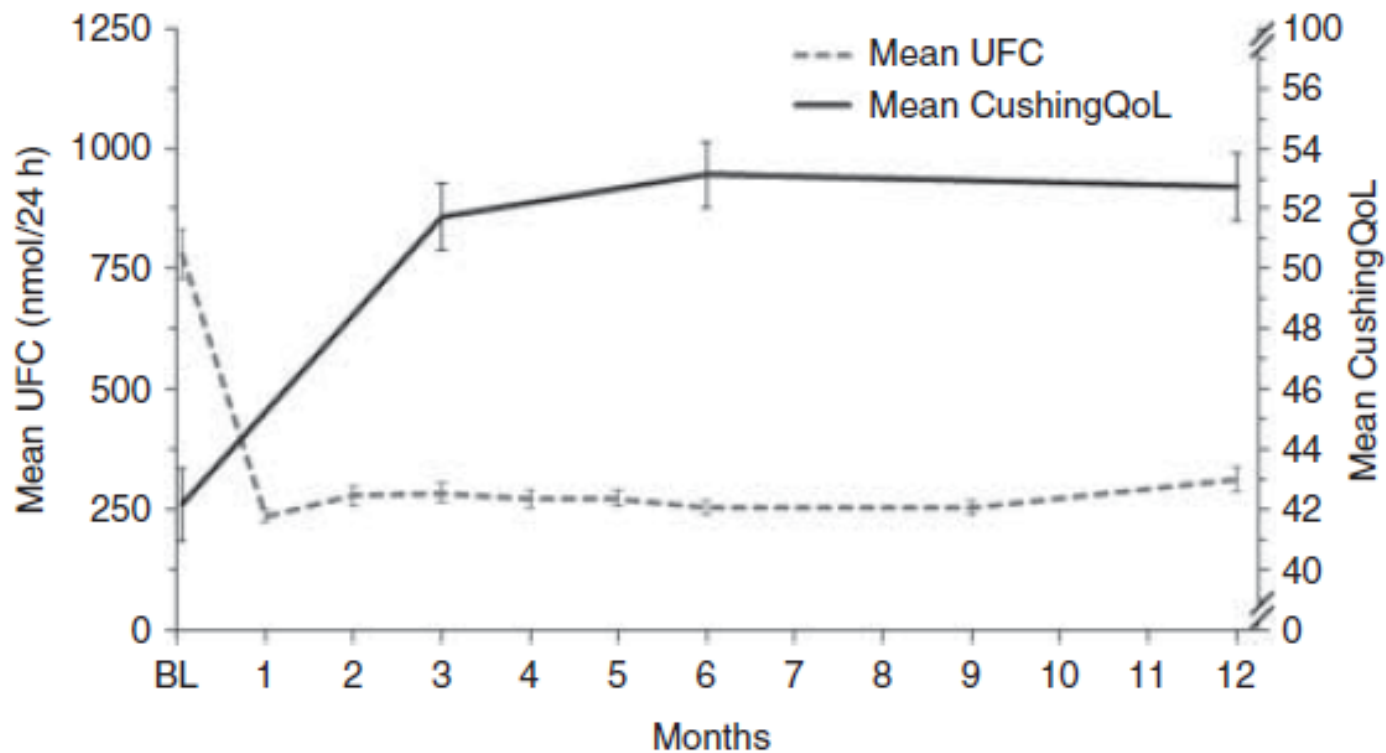
Treatment effectiveness of pasireotide on health-related quality of life in patients with Cushing's disease

Susan M Webb, John E Ware^{1,2}, Anna Forsythe³, Min Yang⁴, Xavier Badia⁵, Lauren M Nelson⁶, James E Signorovitch⁴, Lori McLeod⁶, Mario Maldonado⁷, Wojciech Zgliczynski⁸, Christophe de Block⁹, Lesly Portocarrero-Ortiz¹⁰ and Monica Gadelha¹¹



Treatment effectiveness of pasireotide on health-related quality of life in patients with Cushing's disease

Susan M Webb, John E Ware^{1,2}, Anna Forsythe³, Min Yang⁴, Xavier Badia⁵, Lauren M Nelson⁶, James E Signorovitch⁴, Lori McLeod⁶, Mario Maldonado⁷, Wojciech Zgliczynski⁸, Christophe de Block⁹, Lesly Portocarrero-Ortiz¹⁰ and Monica Gadelha¹¹



HRQoL

12 items with score ranging from 12 (worst) to 60 points (best):

- 1 Ho problemi durante il sonno (mi sveglio di notte, ci metto molto ad addormentarmi..)
- 2 Sento dolore che mi impedisce di svolgere la mia vita con normalità
- 3 Le ferite ci mettono tanto a cicatrizzarsi
- 4 Mi spuntano dei lividi con facilità
- 5 Sono più irritabile, sono soggetto a cambi di umore e bruschi scatti di rabbia?
- 6 Ho meno fiducia in me stesso, mi sento più insicuro?
- 7 Mi preoccupano i cambiamenti del mio aspetto fisico dovuti alla malattia?
- 8 Ho meno voglia di uscire o di incontrare parenti o amici?
- 9 Ho dovuto abbandonare le mie attività sociali o di svago a causa della mia malattia
- 10 La malattia ha ripercussioni sulle attività della mia vita quotidiana come il lavoro o lo studio
- 11 Faccio fatica a ricordarmi le cose?
- 12 La mia salute futura mi preoccupa

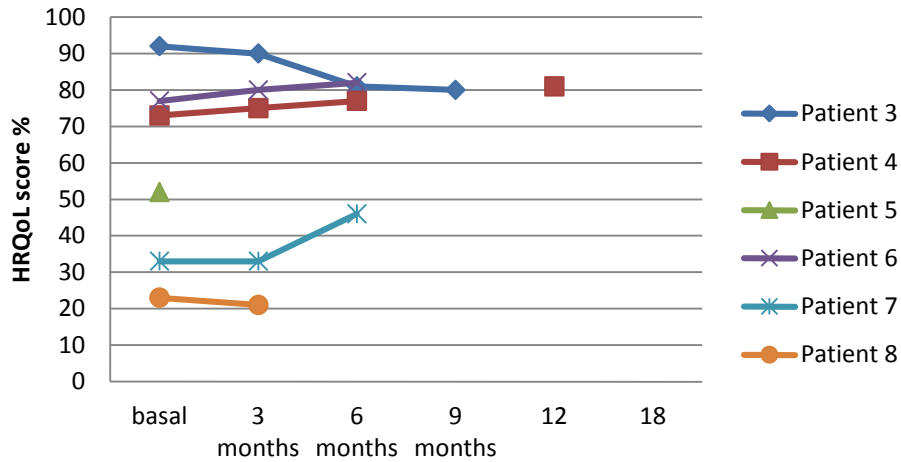
$$Y = \frac{(X) - \min}{(\max - \min)} \times 100$$

PATIENTS

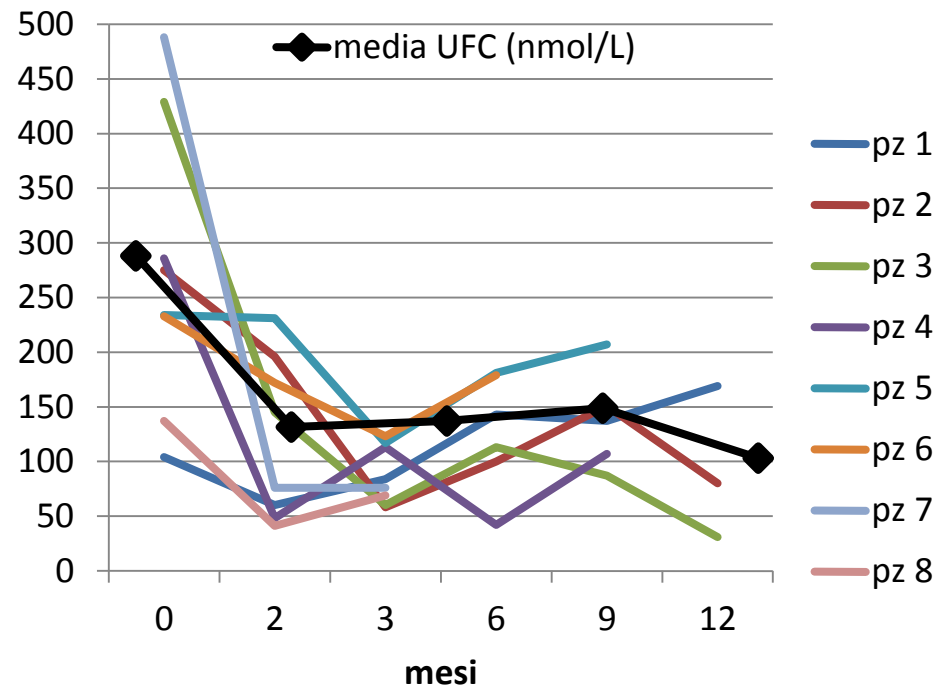
Patients	Sex	Age	Previous treatments	Previous medical therapies	Status
1	F	52	TSS	KET 400 mg/d + CAB 3.5 mg/week	ongoing
2	F	50	2 TSS, RT	KET 200 mg/d	stopped
3	M	61	2 TSS, RT	temozolomide	ongoing
4	M	37	TSS	KET 400 mg/d	ongoing
5	F	67	TSS	KET 200 mg/die + CAB 0.5 mg/week	ongoing
6	M	51	4 TSS, RT	KET 800 mg/die + CAB 2 mg/week, temozolomide	stopped
7	F	48	TSS, RT	KET 400 mg/d + CAB 2 mg/week	ongoing
8	F	54	TSS, RT, left adrenalectomy	KET, aminoglutetimide, SOM230 sc, CAB	ongoing
9	F	61	TSS	KET + CAB	stopped

Our experience

HRQoL



UFC (nmol/24h)



Case 1

- Male patient, 50 years
- **1999:** diagnosis of pituitary pituitary macroadenoma with invasion of cavernous sinus → TSS
- **2004:** second TSS for regrowth; the patients developed complete anterior hypopituitarism
- 2005: RT
- 2012: during follow-up progressive regrowth of the adenoma → patients started temozolomide

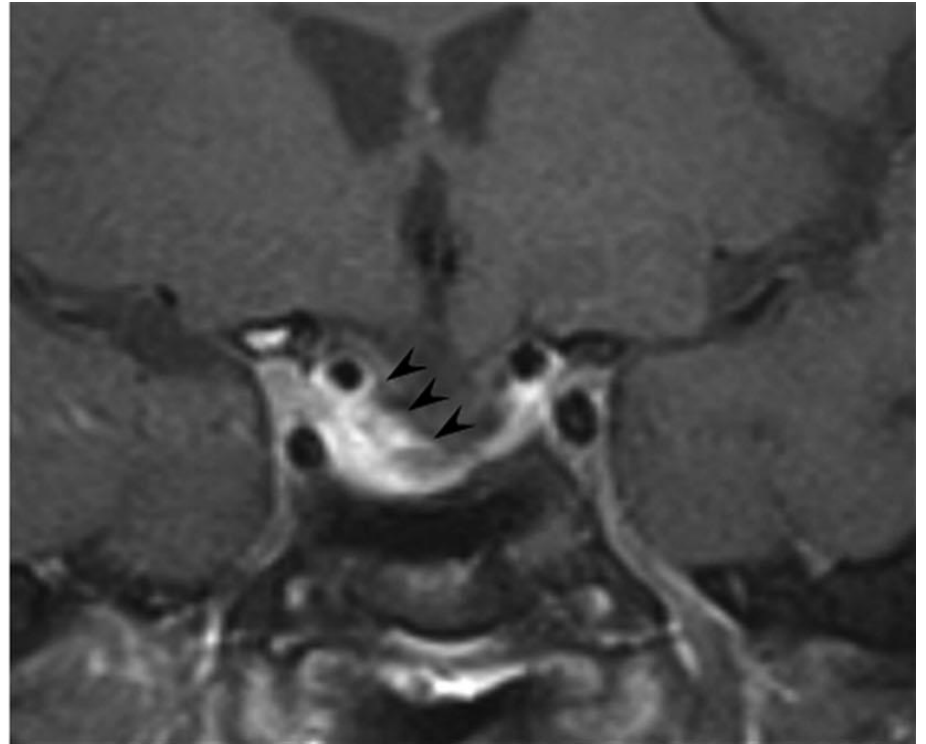
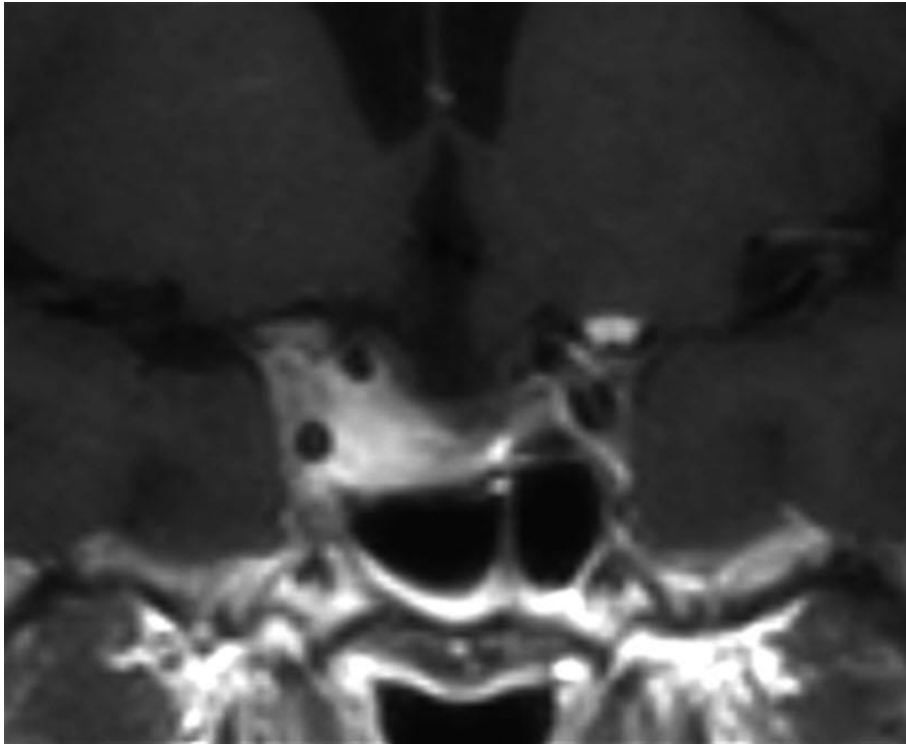


After 12 months of treatment he developed an overt hypercortisolism

Association with pasireotide 600 mcg x 2

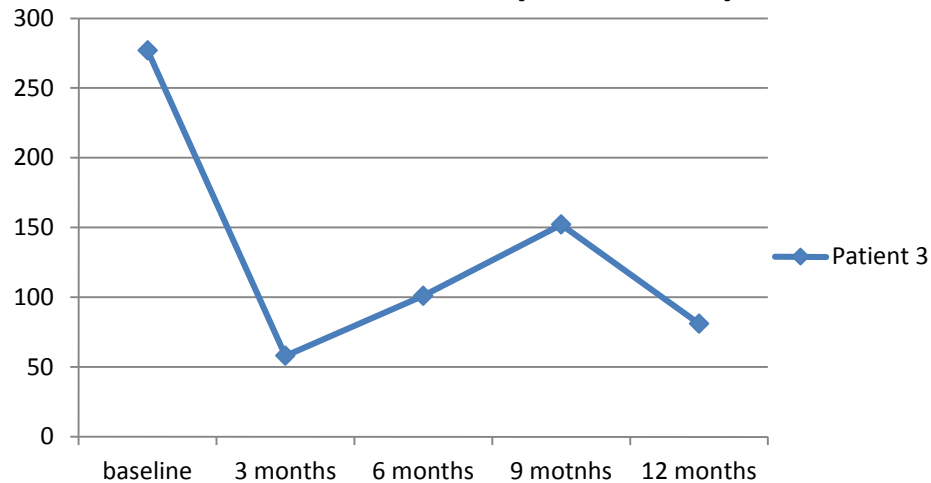
Case 1

Reduction of tumor size after 6 months of treatment

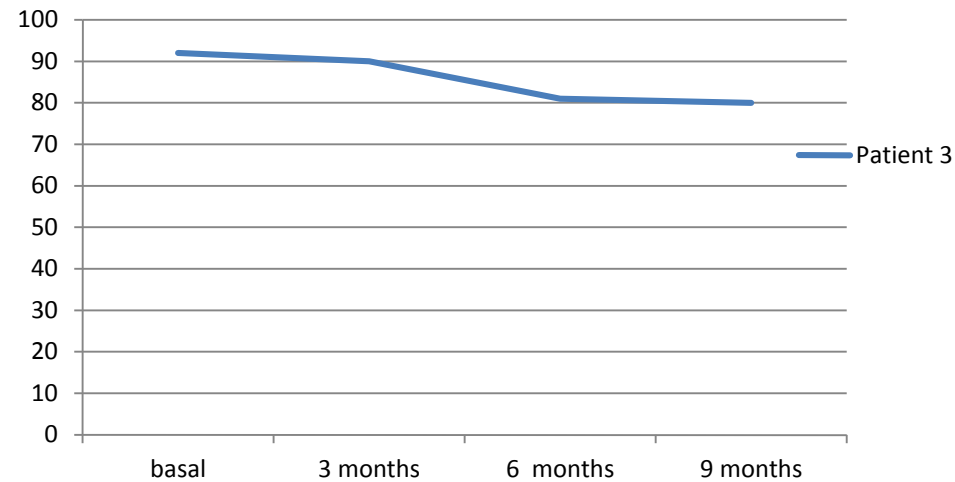


UFC and QoL

UFC nmol/24h (vn 16-168)



HRQoL



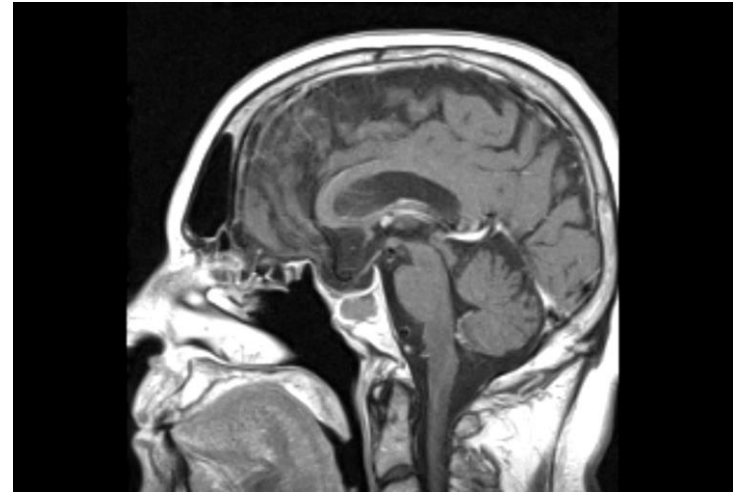
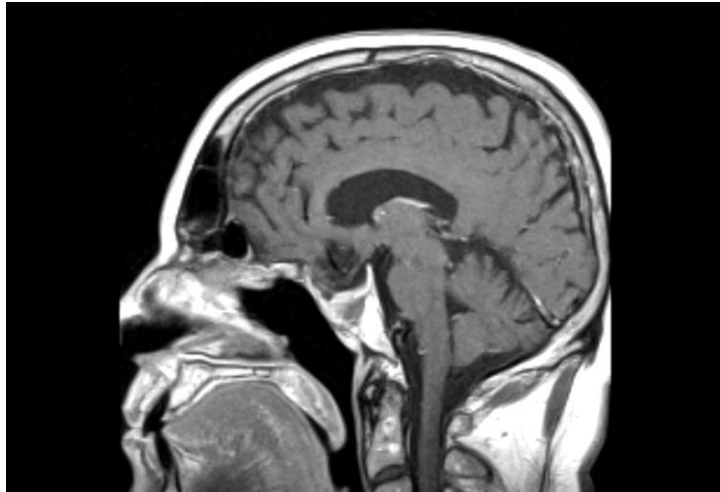
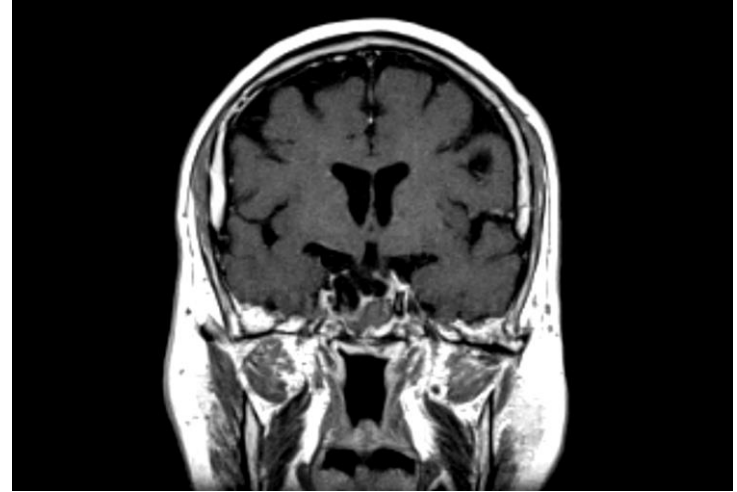
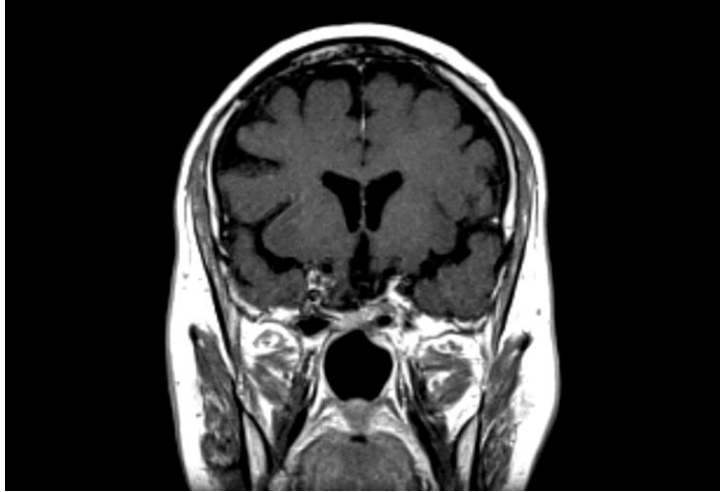
-11%

Why?

Increased number of medications?
Frequent follow-up visits?

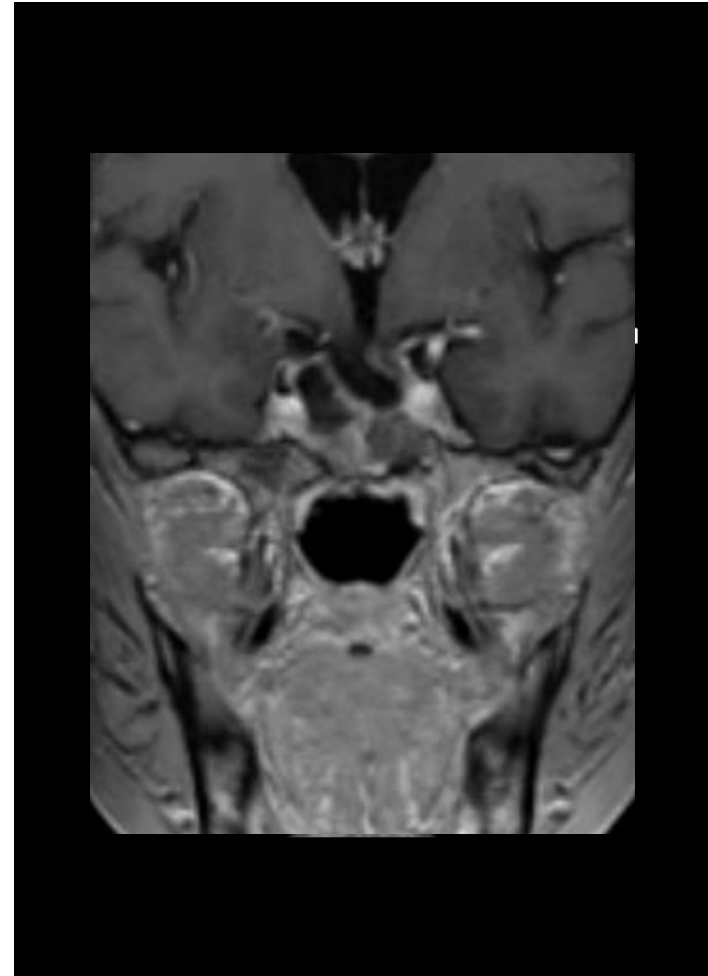
CASE 2

- Male patient, 50 years
- **1999:** diagnosis of CD with pituitary submitted to TSS and subsequent RT for persistence
- **2007:** 2° TSS for intrasellar recurrence
- **2008:** 3° TSS for extrasellar recurrence
- **February 2010:** 4° TSS for intra and extra-sellar recurrence.
- **December 2010:** new tumor increase with overt CD
- **2011:** started temozolomide with complete regression after 24 months



**24 cycles TMZ: Complete response (stop TMZ)
(remission after 6 months from TMZ discontinuation)**

After 12 months something happened



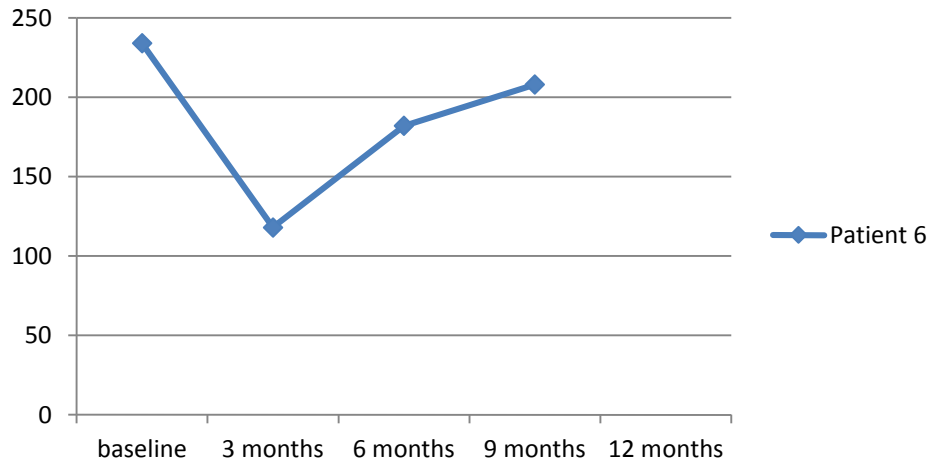
UFC 193 nmol/24h (vn: 16-168), LNSC 4.7 ng/ml,
serum cortisol after 1 mg Dexamethasone: 290 nmol/L

UFC and QoL

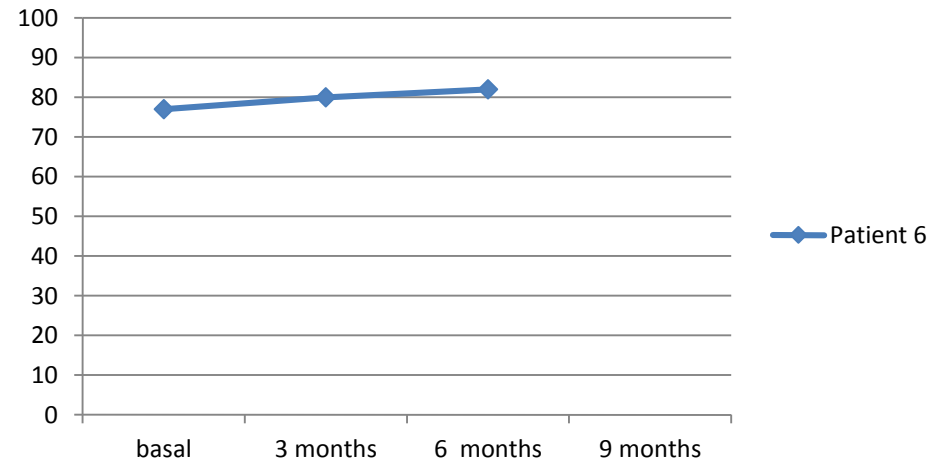
Patient started with pasiretotide 600 mcg x 2/day with UFC normalization

At month 6 the dose was increase to 900 mcg x 2/day

UFC nmol/24h (vn 16-168)

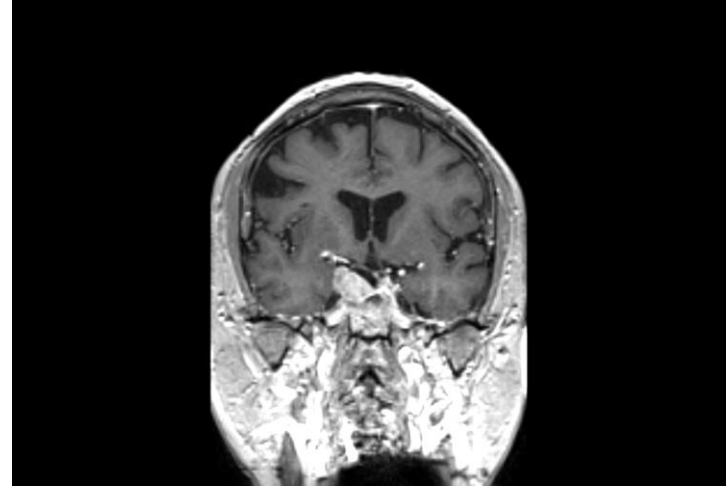
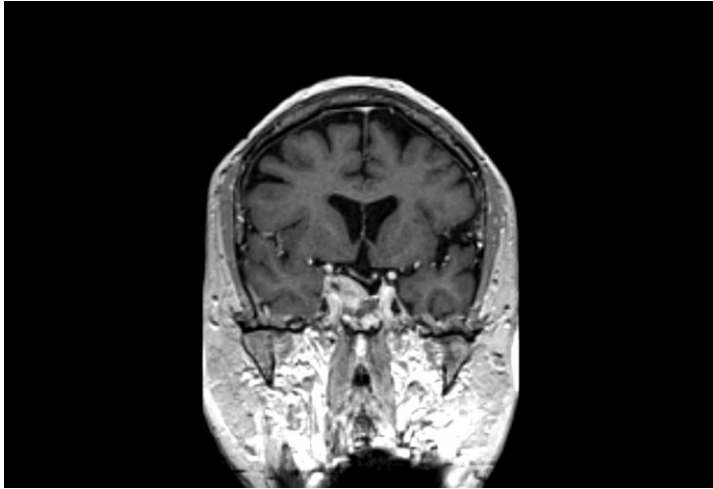


HRQoL



+5%

After 9 months with pasireotide...



Tumor regrowth



Stop pasireotide

