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Recovery of Male Sexual Function and Serum Testosterone After Endoscopic Transnasal Transsphenoidal Resection of Pituitary Adenoma: A Prospective Cohort Study

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ABSTRACT:

Background: Sexual dysfunction is a frequent but under-assessed manifestation of pituitary adenoma in men; this is most often secondary to pituitary-gonadal axis suppression. It is uncertain whether ETTSs reverse such a deficiency; prospective studies using a validated symptom scale together with objective measurement of serum concentrations are uncommon. Herein we assess erectile function and serum testosterone concentration before and after ETTS in men with an ED presentation of pituitary adenoma.

Methods: We conducted this single-center, prospectively collected cohort of 17 consecutive men with pituitary adenoma and ED to have an ETTS. The 5-item IIEF-5 and total testosterone levels were recorded preoperatively and postoperatively and assessed. records of visual fields, extent of surgery, and complications were taken. Paired changes were evaluated with the Wilcoxon signed-rank test, and proportions are reported with a 95% Wilson CI.

Result. The mean age of patients was 44.6 ± 9.8 years. At baseline, patients showed ED, subnormal testosterone, and raised prolactin (15 patients, 88.2%). The mean IIEF-5 increased in all patients by 5.2 [95% CI 4.1-6.3] with an improvement in each case, from a preoperative mean IIEF-5 score of 12.7 ± 3.4 to a postoperative IIEF-5 score of 17.9 ± 3.0 ($p < 0.001$; $r = 0.88$). Overall, testosterone increased from 1.23 ± 0.50 to 2.90 ± 0.57, with 16 patients showing an increase (94.1%); 95% CI 1.23-2.13. Gross total resection was achieved in 16 of the 17 men (94.1%), with complete loss of testosterone only occurring in the one patient not receiving GTR. The change in IIEF-5 did not correlate significantly with the change in testosterone levels (Spearman 0.21, p 0.42). Two complications (11.8%) occurred: 1 CSF leak with associated sinusitis and 1 case of epistaxis, without significant morbidity. No patients suffered injury of vessels or de novo hypopituitarism.

Conclusions: ETTS was associated with reliable regain of sexual function and remarkable rise in serum testosterone with low morbidity. As hormonal regain was unrelated to functional regain, sexual function appears multifactorial. Our conclusion strongly warrants serial evaluation of sexual function preoperatively and postoperatively for any elective pituitary adenoma operation.

INTRODUCTION

Pituitary adenomas are among the more common types of intracranial neoplasms accounting for roughly 10–15% of all intracranial tumors. [1, 12] Though histologically benign, they commonly disrupt hormonal balance due to autonomy and autonomous hormonal function or due to mechanical compression of the normal gland, its stem, and surrounding vessels. This dysfunction is responsible for hypogonadotropic deficiency of the hypothalamo-pituitary-gonadal (HPG) axis, which controls gonadal regulation in men. [1, 2]

Luteinising and stimulating hormone produced from pituitary in response to pulsatile stimulation from hypothalamus secreting gonadalreleasing hormone, in turn induce leydig cell functions like tesosterone production and spermatogenesis in men. These effects are hampered by mass lesions or overstimulation of secreting hormones (most times the case with overproduction of hyperprolactinemia). Hypogonadism, reduced sexual desire, and ED develop as a consequence of disruption of these axes. [2 Erectile dysfunction (ED) is defined as difficulty in establishing or maintaining an erection sufficient for intercourse and causes an amount of anxiety and stress in a patient's personal and sexual life; it's a common complaint brought to a clinician [3, 4, 13]. Specifically in patients with prolactinoma, hormonal excess caused by excessive production of prolactin suppresses testosterone production and acts directly on the sexual centers, causing sexual difficulties; dopamine agonists are still the first-line drugs for the management, and the indication of surgery is for drug failure/intolerance, compression with visual symptoms, apoplexy, or patient will. [5, 14]

With the addition of the endoscope to transsphenoidal surgery [6], endoscopic transnasal transsphenoidal surgery (ETTS) has become the method of choice for sellar lesion operations, with its potential to view the tumor panoramically with possibilities for gland decompression and remaining endocrine function. Nevertheless, whether sexual dysfunctions following the presence of pituitary adenoma were potentially reversible after resection of the tumor has remained relatively poorly defined in prospective trials using a validated quantitative instrument [17, 18]. The 5-item International Index of Erectile Function (IIEF-5) is a valid, internally consistent self-report instrument designed to diagnose and assess severity of ED (rated from 5 to 25 with categories ranging from severe to absent) [7, 13].

On this basis Zhou et al. Retrospectively recorded sexual function in 254 male patients with pituitary adenoma and showed that more than half of patients had pre-operative sexual dysfunctions and that all categories of patients exhibited improvement post-operatively with more relief with complete than partial excision [8]. A prospective randomized clinical trial has confirmed an improvement of sexual activity. Following endoscopic transnasal transsphenoidal surgery in mixed-gender patients [9]. Pre- and post-op hormonal measurement of circulating testosterone in conjunction with the 2 validation instrument sex-variable indices remain limited, however, and the relationship between hormone function recovery and these indices is not perfectly defined [2, 8, 9]. As clinical criteria for men's diagnosis for hypogonadism are based on both biochemical and symptom components, measurement of serum testosterone along with the use of a valid sexuality instrument for the interpretation of this recovery.

We report here the results of a prospective survey of erectile function and circulating testosterone serum in male pituitary adenoma (PA) patients with erectile dysfunction (ED) before and after ETTS. Primary Outcome: IIEF-5 postoperative difference. Secondary outcome measures included serum total testosterone difference, degrees of removal, and adverse events.

METHODS

Study design and setting

We performed a single-center, prospective, single-arm cohort study of consecutive men with pituitary adenoma treated by ETTS at the Department of Neurosurgery, Al-Azhar University Hospitals, Cairo, Egypt. The reporting is according to the STROBE statement for observational studies [16].

Participants

Eligibility criteria: Adult men with pituitary adenoma with pre-operative erectile dysfunction treated by ETTS. Exclusion criteria were: open (transcranial) surgery, recurrent adenoma, prior lumbar discectomy, any genitourinary/urology operation or malignancy, penile implant, erectile dysfunction of other systemic diseases, and any patient who was regularly treated using phosphodiesterase-5-inhibitors (PDEs/5I) or some herbals that have effects on libido, patients who are undergoing chemo/radiotherapy, having other hematological diseases, and those who are lost in follow-up. Seventeen patients fulfilled these criteria and finished the follow-up, all of whom have been considered in the analysis.

Preoperative assessment

All participants were subjected to standard history, examination, sexual-function assessment, hormonal investigations, specific pituitary MR imaging, and paranasal sinus CT imaging to facilitate surgical planning and anophthalmic (including formal perimetry examination). Endocrine tests include adrenocorticotropic hormone (ACTH), insulin-like growth factor-1 (IGF-1), free triiodothyronine (FT3), free thyroxine (FT4), thyroid-stimulating hormone (TSH), basal cortisol level (08:00 h), prolactin (PRL), growth hormone (GH), total testosterone, follicle-stimulating hormone (FSH), and luteinizing hormone (LH). Hormonal values other than testosterone, except for total testosterone at both points, which remained as a total concentration value, were evaluated as categorical with respect to normal reference laboratory limits in our hospital.

Sexual function assessment

The erectile function of the patient was assessed preoperatively on surgery admission day by the IIEF-5 score. On postoperative follow-up, ED grade according to the total score had been categorized as severely moderate (1-7), moderate (8-11), mild to moderate (12-16), mild (17-21), and none (22-25) ED [7].

Surgical technique

All cases were surgically approached by endoscopic transnasal transsphenoidal access. There was a selective adenoma removal with internal debulking, CAPS mobilization, extracapsular neurovascular dissection, tumor retrieval, and a selective removal preserving the normal pituitary gland. The resection extent was GTR or STR according to surgeon findings and imaging follow-up results.

Follow-up and outcomes

Patients were evaluated 6 months after resection with a repeated endocrine test, IIEF-5 assessment, and MRI of the pituitary gland. The main endpoint was a change in the IIEF-5. The secondary outcomes were a change in total serum testosterone concentration, the gross total extent of resection, and the complications after surgery (cerebrospinal fluid [CSF] leak, vascular injury, meningitis, sinusitis, epistaxis, pneumocephalus, intraventricular hematoma, and new endocrine dysfunction).

Statistical analysis

Continuous variables were expressed as mean, standard deviation, and median (range); dichotomous variables as counts and percentiles. Paired change from baseline in IIEF-5 and testosterone was tested using the Wilcoxon signed-rank test, with the standardized effect size given by r=Z/N; paired t tests were conducted as sensitivity analyses. Confidence intervals for mean changes (from t-distribution) and for proportion (from the Wilson method) were 95% CIs.

Associations were examined using Spearman rank correlation, and the difference in change in testosterone levels between resection groups was evaluated with the Mann-Whitney U test (given the size of the sample, these analyses should be considered exploratory).

An uncorrected two-sided p-value less than 0.05 was taken to mean that the result was significant. Analysis was conducted using IBM SPSS Statistics version 19 (SPSS, Chicago).

Ethical approval

The study was approved by the Research Ethics Committee, Faculty of Medicine, Al-Azhar University [approval number and date to be inserted], and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

RESULTS

Baseline characteristics

Seventeen men were included, with a mean age of 44.6 ± 9.8 years (median 42, range 29–64 years). All 17 men (100%) complained of ED by definition. The most prevalent other presentations of hormone dysfunction were headache (n=16/17; 94.1%), visual blurring (n=13/17; 76.5%), and visual field deficits (n=8/17; 47.1%), followed by acromegalic symptoms and diminished libido (n=6/17; 35.3% and n=7/17; 41.2%, respectively; Supplemental Fig. S1).

The most consistent hormone deficiency detected was serum total testosterone that was reduced in 17/17 men (100% by design), followed by hyperprolactinemia (15/17 men; 88.2%).

Only four individuals (23.5%) had elevated IGF-I, one (3/17; 17.6%) had a suppressed cortisol value, and two men (2/17; 11.8%) presented with a suppressed LH value. FSH was elevated in 2/17 men. The LH level was within normal reference in all included men (Supplemental Fig.).

All men had pituitary MRI scans preoperatively as well as paranasal CT. Formal field of vision examinations in 17 men revealed a normal visual field in 8/17 men (47.1%) and an abnormal field in 9/17 men (52.9%); six cases showed a bitemporal hemianopia, and three patients had an abnormal visual field pattern of different types, including one with bitemporal superior peripheral contraction. Table 1 is a comparison of all 17 patient baseline characteristics.

Primary outcome: erectile function

All patients, 17/17, improved 100% in their scores on the International Index of Erectile Function 5 (IIEF-5). Post-operative scores improved from mean values of 12.7±3.4 and median 14 (5-17) pre-operatively, to mean 17.9±3.0 and median 18 (11-22); a difference of mean 5.2 (95% CI 4.1-6.3, Wilcoxon signed-rank test $p<0.001$, standardized effect size $r=0.88$) or from a paired t-test, which came to a similar conclusion ($p<0.001$). Using a severity grouping, prior to surgery the cohort consisted of 70.6% mild, moderate, or more severe EC (12 of 17 patients, of whom 4 , 23.5%, reported moderate to severe issues); after surgery, they became 70.6% mild severity (12/17 patients), one moved to the ED no-score group (22-25), and only one remained in moderate (Figure 1) among the patients, demonstrating a definite improvement. Individual histories also show consistent improvement (Figure 2).

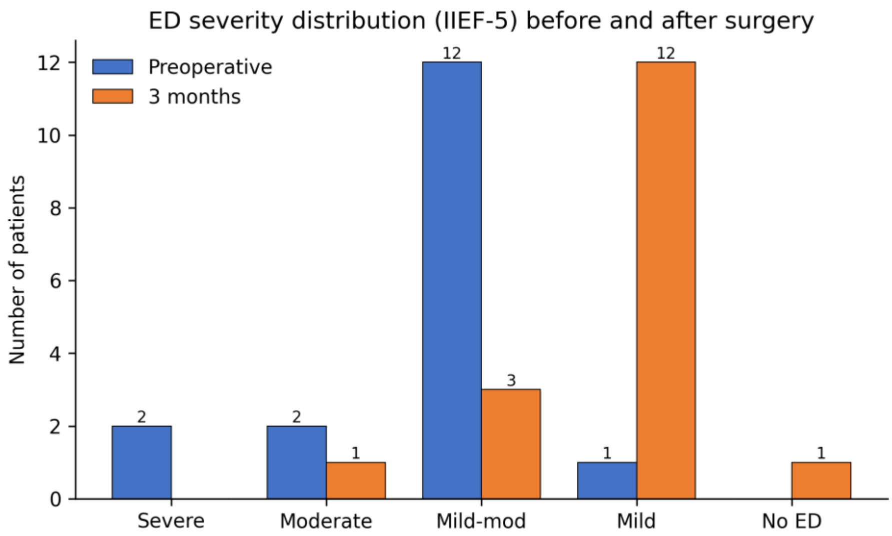

Fig. 1 Distribution of erectile-dysfunction severity by IIEF-5 category before and after surgery (n = 17)

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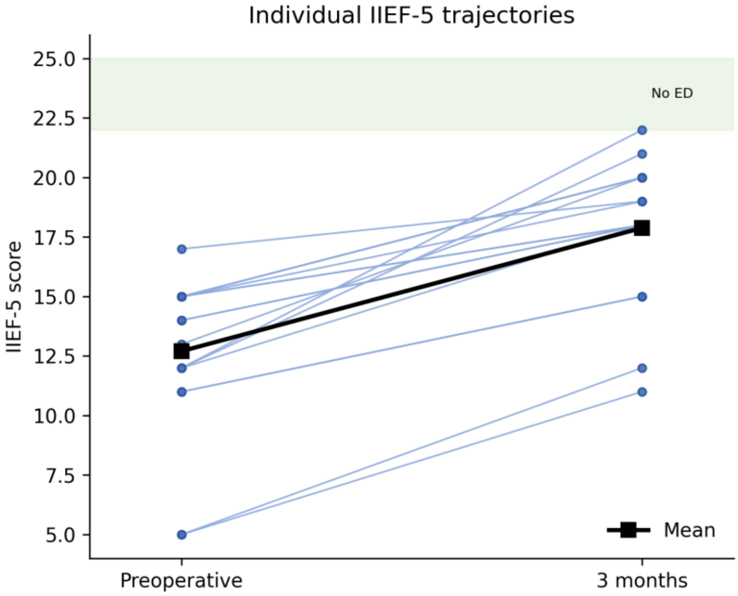

Fig. 2 Individual IIEF-5 trajectories from baseline to postoperative assessment; the bold line denotes the group mean. The shaded band marks the no-ED range (22–25)

Secondary outcome: serum testosterone

Mean serum total testosterone preoperatively increased from 1.23 ± 0.50 (median 1.39; range 0.09-1.90) to postoperatively 2.90 ± 0.57 (median 2.90; range 1.30-3.90) at a mean increase of 1.68 (95% CI 1.23-2.13; median +1.50; range 0.30 to +3.20). The paired change was significant (Wilcoxon signed-rank $p < 0.001$; $r = 0.87$; paired t-test $p < 0.001$). In 16/17 (94.1%; 95% CI 73.0-99.0), testosterone increased to an above-preoperative value, but in one patient it decreased (Fig. 3). The preoperative concentration of no patient increased to 2.5, and postoperatively, 15 patients achieved 2.5, whilst 7/17 (41.2%; 95% CI 22.4-62.7) attained 3.0 and above. Therefore, a considerable part of the cohort did achieve low-normal expected testosterone levels.

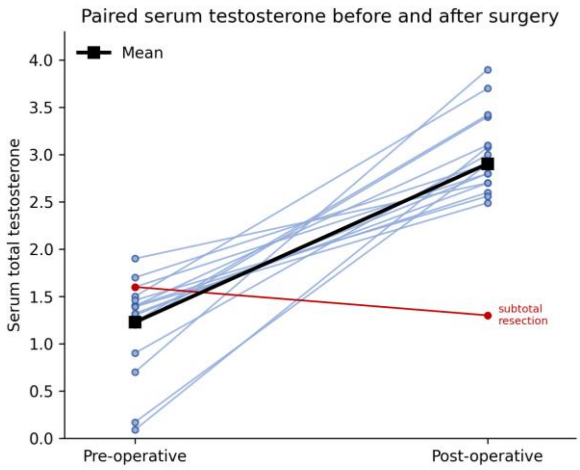

Fig. 3 Paired serum total testosterone before and after surgery (n = 17); the bold line denotes the group mean. The single patient whose concentration fell (red) was the only subtotal resection

Extent of resection and morbidity

Gross total resection was achieved in 16/17 patients (94.1%; 95% CI 73.0–99.0) and subtotal resection in 1 (5.9%). There was a 1.80 average increase of testosterone after GTR compared to a 0.30 decrease after STR. Comparison of testosterone increase between groups did not reach statistical significance (Mann-Whitney p=0.13 and not meaningful with one patient in STR group). Postoperative clinical outcome was judged improved in all 17 (100%) patients.

Complications occurred in 2 (11.8%; 95% CI 3.3-34.3) out of 17 patients, epistaxis in one patient and an intraoperative CSF leak with postoperative rhinorrhea and sinusitis in the other. There was no vascular impairment, nor meningitis, pneumocephalus, intracranial haematoma, or new postoperative hypopituitarism. A summary of outcomes appears in Table 2.

Exploratory analyses

There was no link between the amount of increase in testosterone and the amount of increase in IIEF-5 (Spearman = 0.21; p = 0.42); similarly, there was no correlation between postoperative testosterone and IIEF-5 (=0.14; p = 0.59) (Figure 4). Age did not connect with the degree of recovery (=0.28; p=0.27), although a lower postoperative IIEF-5 was associated with a larger IIEF-5 increase (=0.57; p=0.018). In summary: Younger age groups and initially poor erectile function were the only statistically significant factors that determined success in terms of regaining IIEF-5.

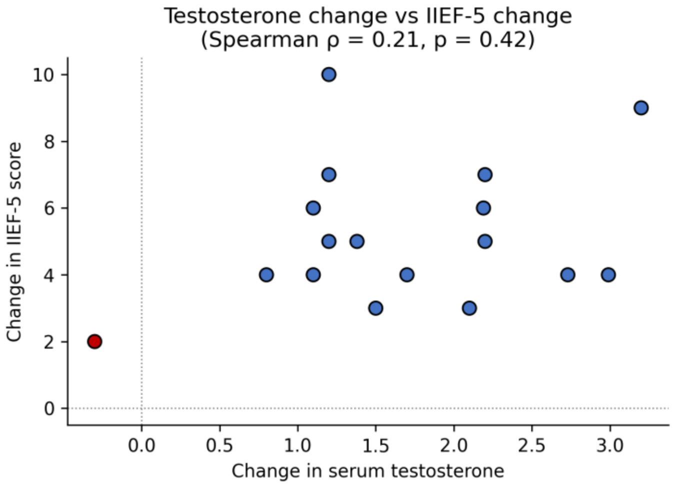

Fig. 4 Change in serum testosterone plotted against change in IIEF-5 score for each patient. The single subtotal resection is shown in red

Table 1 Baseline characteristics of the cohort (n = 17)

Characteristic	Category	Value
Age, years	mean ± SD (median; range)	44.6 ± 9.8 (42; 29–64)
Presenting features, n (%)	Erectile dysfunction	17 (100)
	Headache	16 (94.1)
	Blurred vision	13 (76.5)
	Visual-field defect	8 (47.1)
	Reduced libido	7 (41.2)
	Acromegalic features	6 (35.3)
Perimetry, n (%)	Any field defect	9 (52.9)
	Bitemporal hemianopia	6 (35.3)
	Other field defect	3 (17.6)
Baseline hormones, n (%)	Testosterone below range	17 (100)
	Prolactin elevated	15 (88.2)

Characteristic	Category	Value
	IGF-1 elevated	4 (23.5)
	Cortisol below range	3 (17.6)
	FSH elevated	2 (11.8)
	LH within range	17 (100)
Baseline measures	IIEF-5, mean ± SD (range)	12.7 ± 3.4 (5–17)
	Testosterone, mean ± SD (range)	1.23 ± 0.50 (0.09–1.90)

SD standard deviation, IGF-1 insulin-like growth factor-1, FSH follicle-stimulating hormone, LH luteinizing hormone, IIEF-5 5-item International Index of Erectile Function. Hormone results other than testosterone were recorded categorically relative to the local laboratory reference interval. Testosterone units: [confirm assay units and reference interval].

Table 2 Outcomes after endoscopic transsphenoidal surgery (n = 17)

Outcome	Value	95% CI / p
IIEF-5, preoperative (mean ± SD)	12.7 ± 3.4	—
IIEF-5, postoperative (mean ± SD)	17.9 ± 3.0	—
IIEF-5 change (mean)	+5.2	4.1–6.3; p < 0.001
IIEF-5 effect size (r)	0.88	—
Patients improved on IIEF-5, n (%)	17 (100)	81.6–100
Testosterone, preoperative (mean ± SD)	1.23 ± 0.50	—
Testosterone, postoperative (mean ± SD)	2.90 ± 0.57	—
Testosterone change (mean)	+1.68	1.23–2.13; p < 0.001
Testosterone effect size (r)	0.87	—
Patients with testosterone rise, n (%)	16 (94.1)	73.0–99.0
Gross total resection, n (%)	16 (94.1)	73.0–99.0
Clinical assessment improved, n (%)	17 (100)	81.6–100
Any complication, n (%)	2 (11.8)	3.3–34.3
CSF leak with sinusitis	1 (5.9)	—
Epistaxis	1 (5.9)	—
New hypopituitarism / vascular injury	0 (0)	—

CI confidence interval (Wilson method for proportions), CSF cerebrospinal fluid, SD standard deviation. Paired changes were tested with the Wilcoxon signed-rank test; effect size $r = Z/\sqrt{N}$.

DISCUSSION

Following endoscopic transsphenoidal resection, ED in our group of 17 men with pituitary adenoma and pre-operative ED showed consistent improvement (all showed improvement in the IIEF-5 with a mean increase of 5.2 points) along with increased serum total testosterone (16 of 17 men had higher testosterone). Both showed a large effect size. We had 94.1% successful gross total resection with low morbidity, a complication profile in keeping with contemporary endoscopic transsphenoidal series [19], and only the patient with decreased testosterone had only a subtotal resection. It is likely due to decreased suppression of the HPG-axis: In a prolactin-dominant cohort, such as ours, we have gonandotropin suppression and decreased testosterone due to hyperprolactinemia. We also may have compression on the gonadotroph functions. All of the above can be corrected when the adenoma is removed, thereby resulting in recovery of both testosterone and sexual functions [2, 5, 17, 18]. Since only the one person with subtotal resection had a decline in testosterone, this also fits the observation perfectly. So far we found a similar report, the retrospective study in 254 men by Zhou et al.: All patients who have been operated on and all groups showed an improvement in sexual function in terms of T (which correlated to the degree of improvement of sex life), and all these results were higher in the groups with complete resection of the adenoma than in the patients with only partial resection [8]. We also found similar results, which are more prospective, as we correlated testosterone levels with validated scores and found improvement in both parameters. They found that improved sexual function resulted following ETTS [9].

The most instructive finding was a dissociation. Erectile function improved in all patients, but the level of increase in testosterone patients doesn't relate to the extent of IIEF-5 improvement, and postoperative testosterone did improve with postoperative IIEF-5. Recovery of sexual function following pituitary decompression, therefore, does not appear to be a simple consequence of androgen restoration.

Several mechanisms will, in theory, act in parallel: the conversion to sexual function through the normalization of the prolactin level through a central dopaminergic pathway and a non-androgenic one [2, 14]; decompressing the mass lesion, with visual and headache improvement; and the psychological effect of successful treatment of an intracranial neoplasm [3, 4, 10].

This is in keeping with guidelines that define androgen deficiency through biochemical and symptomatic criteria, which correlate poorly [10, 11, 13, 15]. It also suggests that an 'all clear' postoperative testosterone level does not necessarily confirm sexual recovery, nor does a 'low' result confirm its absence.

A second remark that deserves discussion. Even with significant increases in testosterone, most patients' postoperative levels stayed in the low end of the adult male range, and over half of them failed to reach the high end of what is deemed to be clearly sufficient. It is impossible to determine from this data whether these levels rise further or whether a subgroup is indicated for endocrinology referral with potential androgen replacement [15, 20], even though surgery on this series produced an impressive but frequently incomplete biochemical recovery on long-term follow-up.

The floor effect and regression to the mean occur in comparable quantities, and the inverse association between baseline IIEF-5 and degree of improvement is anticipated. This does not suggest that this study was significantly

STRENGTHS AND LIMITATIONS

Strengths include the prospective nature of the study, dual measurement of both a validated questionnaire instrument and serum testosterone at the time points chosen, perfect follow-up of all eligible patients, and a consistent single-surgeon-based surgical approach in a single institution. Limitations: Several shortcomings should be considered. The sample is small and from a single institution with a ‘no-arm design’; hence, the study could not produce adequately adjusted or multivariable analyses, as subgroups, especially that relating to adenoma resectability, are powered by the value derived from a single patient.

Details of units and range for the test used to quantify the testosterone levels in the study data were absent, so we recorded an absolute value for biochemical re-normalization rather than a normalized rate value.

Non-testosterone endocrine profiles were collected as categorical data, so analysis of prolactin re-normalization was not possible even though hormonal response, particularly prolactin restoration, could, likely, mediate any benefits described. Data pertaining to adenoma functional status/subtype, size, cavernous invasion, and grade were not collected, limiting an assessment stratified by type of adenoma. A short duration of follow-up limits assessing the longevity of any functional/hormonal re-normalization. Lastly, the questionnaire used being self-reported is vulnerable to potential order/expectation effects, especially in the context of postoperative intervention, and is in a 'one-arm design,' unable to differentiate between value achieved by normal variation, ‘non-specific beneficial effects’/placebo responses, or indeed that of actual surgical intervention.

FUTURE RESEARCH

Larger multicenter cohorts that provide quantitative pre- and postoperative measurement of the entire pituitary panel, stratification by adenoma subtype and size, longer follow-up periods, and, when possible, comparison with medical treatment are necessary to determine in whom surgical recovery is likely to be most effective and how durable it may be. Since functional and hormonal recovery were dissociated here, studies measuring prolactin, testosterone, and validated sexual-function measures simultaneously will be particularly informative. Additionally, the inclusion of partner reports and quality-of-life tools will help define the clinical value of improved sexual function after surgery.

CONCLUSIONS

In men with pituitary adenoma and erectile dysfunction, endoscopic transsphenoidal resection was followed by consistent recovery of erectile function and a significant rise in serum testosterone with low morbidity. Recovery of sexual function is independent of the magnitude of the increase of testosterone levels, implying a multifactorial process in restoring potency beyond hormone deficiency. Pre- and post-pituitary surgical assessment of sexual function should be regular, and studies will need to be reproduced in larger groups over a follow-up period to provide sustained objective evidence regarding the efficiency of treatment and appropriate, comprehensive quantitative hormonal screening and restoration therapy.

DECLARATIONS

Abbreviations. ACTH adrenocorticotropic hormone; CI confidence interval; CSF cerebrospinal fluid; CT computed tomography; ED erectile dysfunction; ETTS endoscopic transnasal transsphenoidal surgery; FSH follicle-stimulating hormone; GTR gross total resection; HPG hypothalamic–pituitary–gonadal; IGF-1 insulin-like growth factor-1; IIEF-5 5-item International Index of Erectile Function; LH luteinizing hormone; MRI magnetic resonance imaging; SD standard deviation; STR subtotal resection.

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Authors' contributions. [Confirm.] Study conception and design: [initials]; data acquisition: [initials]; analysis and interpretation: [initials]; drafting of the manuscript: [initials]; critical revision and supervision: [initials]. All authors read and approved the final manuscript.

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Availability of data and materials. The de-identified dataset analysed during the current study is available from the corresponding author on reasonable request.

Ethics approval and consent to participate. Approved by the Research Ethics Committee, Faculty of Medicine, Al-Azhar University [؟؟]. Written informed consent to participate was obtained from all participants. Conducted in accordance with the Declaration of Helsinki.

Competing interests. The authors declare that they have no competing interests.

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Supplementary figures

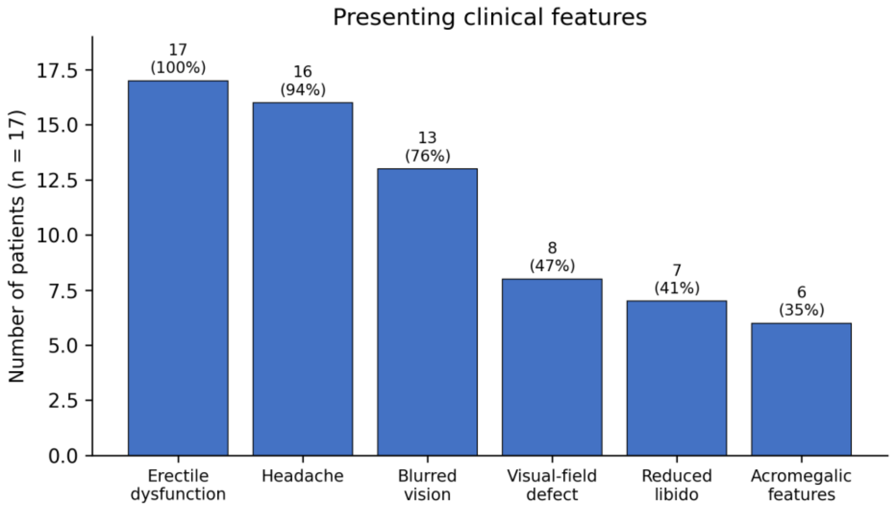

Fig. S1 Frequency of presenting clinical features (n = 17)

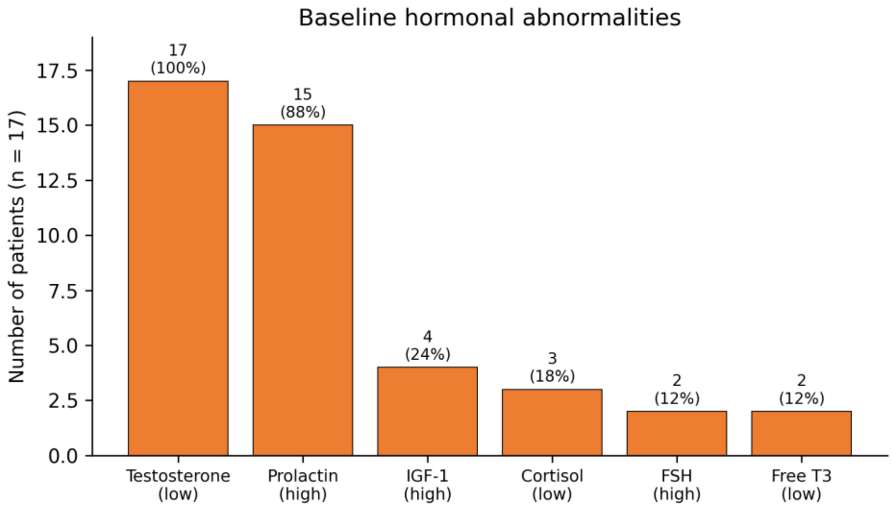

Fig. S2 Baseline hormonal abnormalities