Abstract

Background: Recent advances in the field of endocrinology have led to a better understanding about the etiologies and proper management of erectile dysfunction and male subfertility. Special attention to sexual dysfunction will improve the quality of life and leads to effective treatment of subfertility.

Objective: To study the hormonal profile pattern among Sudanese male subfertility and erectile dysfunction patients.

Materials and methods: In this descriptive study, 600 Sudanese subfertile and erectile dysfunction men attending Al Fordous Andrology Clinic in Khartoum (Sudan) were enrolled during the period from October to December, 2014. Sexual functions of the patients were evaluated by a structural questionnaire, and physical examination was carried out on all patients. Serum luteinizing hormone (LH), follicle stimulating hormone (FSH), prolactin (PRL), estradiol (E2), total testosterone (TES), and total thyroxine (T4) concentrations were measured by the enzyme-linked immuno-sorbent assay (ELISA) technique.

Results: All patients were married for 1-30 years. There was no correlation (p > 0.05) between age and hormones levels in all patients investigated. There was a statistically significant correlation between erectile dysfunction and male subfertility patients as regard FSH (p < 0.00), LH (p < 0.00), PRO (p < 0.00) and E2 (p < 0.00). There was no correlation between these conditions and TES (p > 0.07), or T4 (p > 0.43).

Conclusion: The measurement of FSH, LH, PRO, and E2 hormones was found sufficient to differentiate between erectile dysfunction and male subfertility cases; however, there was no significant TES and T4 correlations with such conditions.

Key words: Hormonal profile, Male subfertility, Erectile dysfunction, ELISA.

Introduction

Erectile dysfunction is the inability to achieve or maintain an erection required for satisfactory sexual action. It affects men's happiness, self-esteem and popular relations; and may contribute
Subfertility is the inability to reproduce by natural means. There are many biological causes of subfertility that can be treated by medical intervention. Subfertility rates have increased by 4% since the 1980s, mostly from problems related to an increase in age. About 40% of the issues involved in subfertility may be due to a male factor, and about 20% may result from complications with both male and female factors.

Understanding the dynamics of endocrine changes in the aging male is important not only to pursue the important role of hormones played in the maintenance of sexual characteristics and sexual activity, but also to diagnose and manage endocrine and metabolic diseases. Data concerning the influence of age on androgens are inconsistent.

This study, to our knowledge was the first trial conducted in Sudan. The object of the study was to clarify the association of age parameter and the endocrine hormones with male subfertility and erectile dysfunction.

**Materials and methods**

This is a descriptive, qualitative, cross-sectional, analytical, and hospital-based study. 600 subfertile and erectile dysfunction men referred to the Fordous Andrology Clinic in Khartoum (Sudan) were enrolled in this study during October to December, 2014; after taking their verbal consent. Inclusion criteria were males being ≥ 20 years old. Erectile dysfunction patients selected had a regular sexual life with their wives; and were clinically diagnosed as such for the previous 6 months. Subfertile males selected for the study had a regular sexual life with their wives for at least one year. Patients with a history of previous pelvic surgery, pelvic irradiation, chronic neurological disease, hypogonadism, or those who were on medication during the recruitment period were excluded from the study. All patients completed a detailed structural questionnaire; and sexual functions were evaluated by including questions on libido, penile erection, orgasm, and frequency of sexual act. Physical examination was carried out to elicit signs of androgenic deficiency.

4 ml venous blood specimens were collected in plain containers from all cases studied. Serum was separated by centrifugation for 5 minutes at 3000 rpm. Serum luteinizing hormone (LH), follicle stimulating hormone (FSH), prolactin (PRL), estradiol (E₂), total testosterone (TES), and total thyroxine (T₄) concentrations were measured by the sandwich enzyme-linked immunoabsorbent assay (ELISA) technique.

This technique was used to identify the specific specimen’s antigens. The well surface of the test plate was prepared with a known quantity of bound antibody to capture the desired antigen. Then nonspecific binding sites were blocked using bovine serum albumin, and the antigen-containing specimen was applied to the plate. A specific primary antibody was then added to sandwich the antigens. Enzyme-linked secondary antibodies were applied to bind to the primary antibodies. Unbound antibody-enzyme conjugates were washed off. Substrates were added and they were enzymatically converted to a quantified color.

Data were expressed as the mean ± standard deviation (SD) and the range or frequency, as appropriate. For analytical purposes, patients were divided into two groups: the erectile dysfunction group and the subfertility group.

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dysfunction group (300 men) and the subfertile group (300 men). Intergroup comparisons were performed using a test for categorical variables and the independent t-test was used for continuous variables. Subsequently, a multivariate linear regression analysis was performed to investigate the potential factors associated with hormonal profile. In addition the Chi-square test was used to compare the age groups with the hormonal profiles. All statistical analyses were performed with the statistical package for Social Sciences Statistical Software (SPSS version 20; IBM, Chicago, IL).

Results:

A total of 600 patients (300 erectile dysfunction males and 300 subfertile males) within the age range 20-70 years were enrolled in the study. All patients were married for 1-30 years. The mean hormonal profiles for erectile dysfunction and subfertility were: FSH (6.94 and 11.432 µg/L), LH (6.23 and 7.82 IU/L), PRL (8.56 and 10.91 pmol/L), E2 (26.31 and 26.12 pg/mL), TES (5.28 and 5.39 nmol/L), and T4 (7.76 and 7.84 µg/dL) respectively (Table I).

Table (I): Mean hormonal profiles for erectile dysfunction and subfertility patients investigated

<table>
<thead>
<tr>
<th>Patients</th>
<th>LH IU/L</th>
<th>TES nmol/L</th>
<th>T4 µg/dL</th>
<th>PRO pmol/L</th>
<th>E2 pg/mL</th>
<th>FSH µg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erectile dysfunction</td>
<td>Mean</td>
<td>6.23</td>
<td>5.28</td>
<td>7.76</td>
<td>8.56</td>
<td>26.31</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>3.87</td>
<td>1.55</td>
<td>2.29</td>
<td>4.30</td>
<td>5.18</td>
</tr>
<tr>
<td>Subfertility</td>
<td>Mean</td>
<td>7.81</td>
<td>5.39</td>
<td>7.84</td>
<td>10.91</td>
<td>26.12</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>7.34</td>
<td>3.64</td>
<td>2.25</td>
<td>9.57</td>
<td>13.18</td>
</tr>
<tr>
<td>Total</td>
<td>Mean</td>
<td>7.02</td>
<td>5.34</td>
<td>7.79</td>
<td>9.74</td>
<td>26.22</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>5.91</td>
<td>2.79</td>
<td>2.27</td>
<td>7.51</td>
<td>10.01</td>
</tr>
</tbody>
</table>

Legend: FSH: Follicle stimulating hormone; LH: Luteinizing hormone; PRO: Prolactin; E2: Estradiol; TES: Total testosterone; T4: Total thyroxine SD: Standard deviation.

As shown on Table (II), there was a statistically significant hormonal profile correlation between erectile dysfunction and male subfertility patients as regard FSH (p < 0.000), LH (p < 0.000), PRO (p < 0.000) and E2 (p < 0.000). However, there was no correlation between these conditions and TES (p > 0.072), or T4 (p > 0.431).

High levels of FSH (>12.9 µg/L), LH (>9.5 IU/L), and PRO (>17.5 pmol/L) were

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more frequent (66/22.0%, 60/20.0%, 18/6.0%) in subfertility patients respectively. On the other hand, the frequency rate of low TES and low E2 was almost similar in both erectile dysfunction and subfertility patients (Table III).

Table (II): Correlation of hormonal profile between erectile dysfunction and male subfertility patients

<table>
<thead>
<tr>
<th>Patients</th>
<th>FSH</th>
<th>LH</th>
<th>PRO</th>
<th>E2</th>
<th>TES</th>
<th>T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correlation between Erectile dysfunction and subfertility</td>
<td>p&lt;0.000</td>
<td>p&lt;0.000</td>
<td>p&lt;0.000</td>
<td>p&gt;0.072</td>
<td>p&gt;0.431</td>
<td></td>
</tr>
</tbody>
</table>

Legend: FSH: Follicle stimulating hormone; LH: Luteinizing hormone; PRO: Prolactin; E2: Estradiol; TES: Total testosterone; T4: Total thyroxine

Table (III): High and low hormonal levels in erectile dysfunction and subfertility patients investigated

<table>
<thead>
<tr>
<th>Patients</th>
<th>High FSH</th>
<th>High LH</th>
<th>High PRO</th>
<th>High E2</th>
<th>Low TES</th>
<th>Low T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erectile Dysfunction</td>
<td>8 (10.4%)</td>
<td>10 (12.9%)</td>
<td>108 (12.9%)</td>
<td>0 (0%)</td>
<td>81 (36.7%)</td>
<td>4 (1.3%)</td>
</tr>
<tr>
<td>Subfertility</td>
<td>66 (22.0%)</td>
<td>60 (20.0%)</td>
<td>18 (6.0%)</td>
<td>4 (2.7%)</td>
<td>155 (51.7%)</td>
<td>3 (0.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>74 (19.6%)</td>
<td>70 (18.6%)</td>
<td>26 (4.3%)</td>
<td>4 (2.6%)</td>
<td>291 (48.5%)</td>
<td>7 (1.2%)</td>
</tr>
</tbody>
</table>

Legend: FSH: Follicle stimulating hormone; LH: Luteinizing hormone; PRO: Prolactin; E2: Estradiol; TES: Total testosterone; T4: Total thyroxine

Most erectile dysfunction subjects (81 patients) were in the age range 51-60 years (27%); while most subfertile subjects (90 patients) were also in the age range 51-60 years (30%). For all patients investigated the mean age was 45 years. There was no correlation ($p > 0.05$) between age and hormone profile levels in all patients studied.

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Discussion

Understanding the dynamics of endocrine changes in the normally aging male is necessary not only because of the important role played by hormones in the maintenance of sexual characteristics and sexual activity, but also for the diagnosis and management of endocrine and metabolic diseases. Data concerning the influence of age on androgens are inconsistent. Several researchers have reported a decrease in total testosterone concentrations, whereas others have failed to find age-related changes in testosterone. This decline with age is related to a decrease in Leydig cell mass, decreased testicular perfusion with relative hypoxia and alterations in pituitary-hypothalamic function.

In our study there was no correlation \((p > 0.05)\) between age and hormone profile levels in all patients studied; and we could not find any statistically significant correlation between age ranges and the value of total testosterone. Our data on this scale were similar to Davidson et al\(^6\) who found no correlation between hormonal profile and age incidence. Fahmy et al reported that it is very difficult to establish a correlation between erectile dysfunction and serum testosterone levels; and demonstrated that low serum total testosterone levels indicate hypogonadism\(^7\). In this study we also found no significant correlation between erectile dysfunction and the level of total testosterone (Table II).

Prolactin levels were found by Rosen et al\(^8\) to have a significant relation with erectile dysfunction. Similar result was also obtained in our study where prolactin was found statistically significant as regard erectile dysfunction.

It has been suggested by Ansong and Punwaney\(^9\) that only the measurement of FSH, LH, PRO, and E were sufficient to differentiate between erectile dysfunction and male subfertility. In our study the hormones FSH, LH, PRO, and E\(_2\) were also found significantly correlated to male subfertility; and this suggests that the differential diagnosis between erectile dysfunction and male subfertility may be based on hormonal levels of FSH, LH, PRO, and E\(_2\).

Furthermore, in our study full medical history was taken and adequate physical examination was carried out on all patients investigated. Such a practice prior to hormonal determination was also conducted by Vekemans and Robyn\(^10\) who advocated this practice and reported that it might help in good evaluation of erectile dysfunction and male subfertility; and can decrease the need for excessive studies and consultations, saving patients time and unnecessary costs.

Conclusion: The measurement of FSH, LH, PRO, and E\(_2\) hormones is sufficient to differentiate between erectile dysfunction and male subfertility; however, there is no significant correlation with erectile dysfunction cases and the levels of TES and T\(_4\) hormones.

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References