



Replacement of testosterone transdermally in male patients with hormone deficiency

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Abstract

Introduction: There is a significant concern about the importance of the condition known as male climacteric or Andropause. In men this process is not universal, occurring in a portion of the male population with more gradual clinical manifestations than those occurring in menopausal women. **Objective:** The present study aimed to evaluate the percentages in testosterone levels before and after the use of transdermal testosterone gel in adult men in Belo Horizonte - MG. **Methods:** The research subjects were men, Penchel Clinic patients

admitted in 2017. As inclusion criteria, men would need to be between 19 and 55 years old and total testosterone measured below 320ng / dl, which characterizes the hormone insufficiency. After 60 days of hormone use, men underwent biochemical reevaluation to analyze testosterone values. Results: From data collection, it was observed that 100% of patients had their testosterone levels increased. The mean value of blood testosterone levels before transdermal gel use was: 278.54 ng / dl, while the mean value calculated after use was 567.59 ng / dl ($p = 0.0000000445$). **Conclusion:** Care for testosterone-deficient patients should focus on accurate assessment of total testosterone levels, symptoms and signs, as well as appropriate monitoring during treatment to ensure that therapeutic levels of testosterone are achieved and symptoms are improved.

Introduction

According to Liberman, Garcia and Figueira (2010) since ancient times the importance of the testicles in the conservation

of virility, physical strength and masculine behavior was already recognized. Two thousand years BC, the Assyrians used castration as a penalty for sexual offenses. The Orientals used eunuchs to take care of the harem, while the Chinese used extracts of testicles for the treatment of impotence.

Hypogonadism in man is due to a decrease in one or both testicular functions - sperm production or testosterone production by a change in primary or secondary level of the hypothalamic-pituitary-gonadal axis. Still in agreement with the authors, unlike what happens with the woman, the bankruptcy of sexual hormones is not abrupt and complete, and when it happens it happens slowly and progressively. Therefore, we should refer to this process not as an andropause, but as a syndrome composed of various symptoms and signs. Therefore, late-onset hypogonadism (LOH) or partial androgen deficiency of the elderly male (PADAM) are more appropriate.

For Burns-Cox and Gingell (2011) the study of andropause symptomatology questions whe-

ther it would be fiction or fact that the term “andropause”, as well as menopause, suggests a hormone deficiency state secondary to gonadal insufficiency and the similarity of the two tends to give credence to the unproven andropause.

The etiology of this age-dependent testosterone decline is multifactorial involving primary testicular abnormalities, dysfunction of the neuroendocrine regulation of gonadotropins, increased serum concentrations of sex hormone-binding globulin, and reduced sensitivity of androgen receptors. Senescence is followed by a series of signs and symptoms, many of which are analogous to those observed in young hypogonadal patients. Such a complex clinical picture may derive from the joint effects of the process of senescence itself and of intercurrent diseases. However, there is evidence that the decline in age-specific testosterone levels is, at least in part, a co-determinant of this clinical picture, since androgen replacement has shown favorable effects in more than 30% of these symptomatic elderly.

According to Martits and

Costa (2004) all strategies for hormone replacement were directed mainly to the treatment of menopausal women. However, the use of hormone replacement therapy with testosterone for the treatment and prevention of andropause has aroused the interest of researchers and clinicians.

McNicholas et al. (2003) report that the use of androgen replacement therapy in hypogonadal men is well documented, especially since the restoration of testosterone concentrations within normal limits retains sexual characteristics, energy, mood, muscle mass development and increase in bone mass.

According to Wu, Tajar, Pye et al. (2008), testosterone concentrations in men decrease with increasing age. Many symptoms and conditions similar to those due to low testosterone levels in men with pituitary or testicular disease become more frequent with increasing age. Such symptoms include reductions in mobility, sexual function, and energy. These parallels suggest that lower levels of testosterone in older men may contribute to these conditions.

For Wang et al. (2011) hormone replacement with testosterone results in an increase in bone mineral density, reducing serum concentrations of markers of bone resorption, and increasing markers of bone formation in hypogonadal, young and old men.

Ly et al. (2011) report that men with late male hypogonadism have a significant increase in bone density in the lumbar spine and hip after testosterone replacement.

Testosterone replacement is able to increase lean mass and lower limb strength and reduce fat mass in young and old hypogonadal men, according to Wang et al. (2011).

This descriptive, quantitative and qualitative, observational study is justified by the fact that, in the current literature and in recent studies, it has been observed that patients who present laboratory abnormalities, signs and symptoms of testosterone deficiency, submitted to hormone replacement via transdermal.

Materials and Methods

Nature of Research

This is a descriptive, quantitative and qualitative, observational study carried out in the medical records of the Penchel Clinic, in order to analyze the rate of transdermal hormone replacement.

According to Pereira (2012) in observational studies, there is no intervention performed by the investigator, what happens is the investigation of situations that occur normally. According to Gil (2010), descriptive research aims to describe the characteristics of a population or a phenomenon, or to establish relations between variables.

The mixed method procedure suits the need to gather both quantitative and qualitative data in a study, expanding the discussion of the need for a research to explore and at the same time explain the phenomena studied.

Ethical Aspects

The project was evaluated and approved by the Ethics Committee of Potiguar University, under the number of opinion 3,113,829.

The data collection was done in the medical records of the Penchel Clinic, after approval by the committee, obeying the norms of Resolution 466, of December 12, 2012, of the National Health Council (CNS).

Access to research data was made after the signature of the data commitment commitment, with a commitment to respect the privacy and confidentiality of the data, preserving the anonymity of the subjects, as well as to use the materials and data collected exclusively for research purposes and should be published to the local community and in the means of disseminating scientific papers. The data were collected after authorization of the institution, through the signing of the letter of consent and the authorization of the institution for file use.

Period and field of study

The study was carried out during the year 2018, from the data collection stages to the final writing of the work. The research

was carried out in the medical files of the Penchel Clinic in the city of Belo Horizonte - MG.

Research Subjects

The subjects of the survey were men, patients of the Penchel Clinic admitted in 2017. As inclusion criteria, men would need to be between 19 and 55 years old and total testosterone measured in values lower than 320ng / dl, which would characterize hormone insufficiency.

As exclusion criteria are men with age that differ from the intended range, in addition to total testosterone levels higher than defined.

Testing for testosterone use

It was verified in medical records that all the men in this study used a bioidentical testosterone base at 2% (20mg) on a transdermal gel, twice a day. The guidelines for using testosterone were as follows: cream should be given by the patient on clean, dry, healthy and hairless skin twice a day in the internal

arm or thigh or abdomen, in uni-directional application, without rubbing the region of application.

After 60 days of hormone use, the men underwent biochemical reassessment for analysis of testosterone values.

Sampling

The sample was defined from the calculation of simple random sampling, considering a 95% confidence interval and 5% margin of error and a universe of 49 men.

Collection and analysis of data

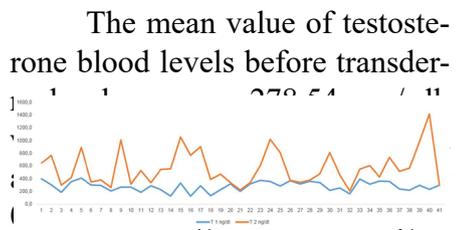
A total of 41 charts were analyzed at the Penchel Clinic during the months of July and August of 2018. The mean age of the study participants was 36 years, so that the youngest was 19 years old and the oldest 55 years, according to previously included inclusion criteria settled down. Statistical analysis of the data related to the changes in testosterone levels were submitted to a significance analysis obtained by the

t test, bilateral, paired with 95% confidence interval. The values were analyzed and obtained in Microsoft Excel® software. Considering the biases associated with studies of this nature, the mean values of each analysis are presented and only then the significance value between these two analyzes. The lower the value of p, statistically speaking, the more reliable the variation between the analyzed numbers.

Results

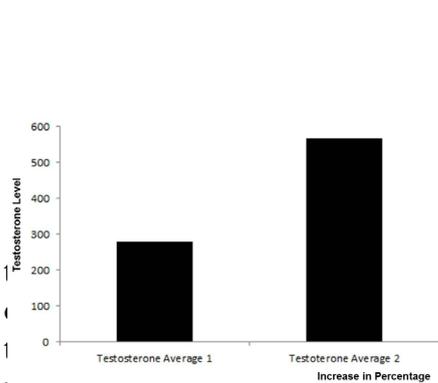
From data collection, it was observed that 100% of the patients had their testosterone levels increased (Graph 01).

Graph 01: Testosterone values before and after transdermal use (T1 - prior to use of transdermal testosterone / T2 - after).



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Graph 2: Mean values (ng / dL) of testosterone levels before and after the use of transdermal gel by the patients under study.

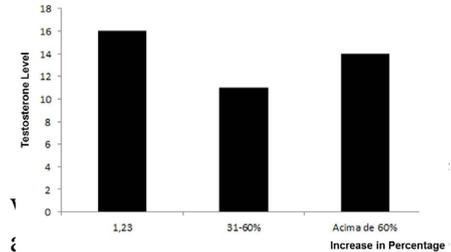


from the use of the transdermal gel.

In percentage, elevations fluctuated between 1.23% (increased from 296.8 to 300.5 ng / dL) and 83.85% (from 124.0 to 768.0 ng / dL), so that the mean value was 41.28%. It is important to consider that at least 7 patients had plasma levels lower than 200ng / dL before initiating testosterone therapy, and that at least 43% of them (n = 3) had grade I obesity (Graph 03).

Graph 03: Percent increase of testosterone levels after the use of the transdermal gel.

ne levels after the use of the transdermal gel.



day analysis, they found that once-daily topical application of 2% testosterone gel restored normal testosterone levels by more than 75% of men with hypogonadism and low risk of comorbidities.

It provides constant levels throughout the day, with an increase ranging from 438.6 ng / dL to 827.6 ng / dL at day 90 of use.

If we stratified the analysis of the increase of testosterone, it was identified that 14 patients had their testosterone levels elevated by more than 60%; 11 patients were in the range of 31 - 60%; and 16 had their levels elevated by up to 30%.

For Dobbs et al. (2009) the time at which serum testosterone concentration should be measured will depend on the testosterone preparation used. With transdermal patches, serum testosterone concentrations fluctuate over the 24-hour period, with a peak value 6-9h after application and nadir (about 50% of peak) immediately prior to application of the next patch.

Ko and Kim (2011) report that andropause has been widely considered in recent years by medical societies. Some studies of testosterone therapy have reported significant progress in reducing symptoms.

According to Laouali et al. (2018) low levels of total and bio-available testosterone are associated with increased all-cause mortality in older men with metabolic syndrome (MS). The authors report in their study that this increased risk of mortality is also seen in men who suffer from testosterone deficiency compared to those with normal or high hormone levels.

Wu et al. (2008) report that testosterone concentrations in men decrease with increasing

age. Many symptoms and conditions similar to those caused by low testosterone levels in men with pituitary or testicular disease become more common as aging. Such symptoms include decreases in mobility, sexual function and energy. These parallels suggest that lower levels of testosterone in older men may contribute to these conditions.

According to Mulhall et al. (2018) care of testosterone deficient patients should focus on accurate assessment of total testosterone levels, symptoms and signs, as well as appropriate monitoring during treatment to ensure that therapeutic levels of testosterone are achieved and symptoms are improved.

Conclusion

Care for testosterone-deficient patients should focus on accurate assessment of total testosterone levels, symptoms and signs, as well as appropriate monitoring during treatment to ensure that therapeutic levels of testosterone are achieved and symptoms are improved.

Conflict of Interest Statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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