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BACKGROUND

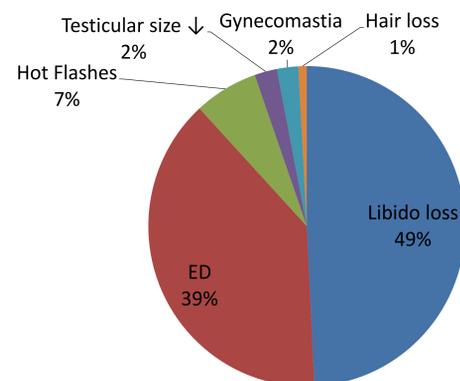
- Currently, the treatment of hypogonadism is based on guidelines that define a lower limit of serum testosterone level.
- There is variation of definition of the lower limit of total testosterone (TT) ranging from 200-350 ng/dl and free testosterone (FT) from 5-10 ng/dl. Insurance companies determine eligibility of treatment based on these guidelines.
- Our study looks at patients who seek treatment at the Low T Centers that have borderline low TT between 350-450 ng/dl and who may not qualify for treatment.

MATERIALS & METHODS

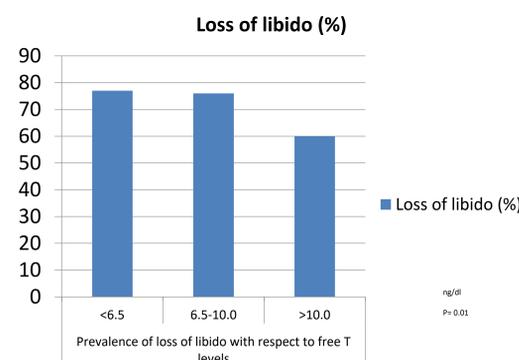
- In this retrospective study, blinded data was extracted from EMR (Advanced MD).
- As screening for eligibility for treatment, besides having blood work for testosterone levels, patients complete a form determining primary and secondary symptoms relating to hypogonadism.
- TT was determined initially using the Qualigen[®] competitive chemiluminescence method and confirmed, if needed, on LC/MS. FT is calculated using the Vermuelen algorithm.
- Patients with TT 350-450 and requiring a symptom checklist by insurance in 42 clinics across the U.S. from June-November 2015 were included. Data was entered into an Excel spreadsheet and descriptive and comparative analysis applied.

RESULTS

- Our study group (n=593) were males, with a mean TT = 394 ng/dl (range 350-450) and mean FT= 7.0 ng/dl (range 3.3-13.7).
- In this group, we found a high percentage of patients with primary symptoms of loss of libido (86%) and loss of spontaneous erections (68%). Less common primary symptoms were hot flashes (11.4%), decreased testes size (4%), gynecomastia (3.8%), and hair loss (1.5%). Less specific secondary symptoms such as fatigue, mood, mental and weight changes were however very common.
- Of the patients that had TT between 350-450 ng/dl; 41% had FT < 6.5 ng/dl and 96% had < 10 ng/dl.
- 77% of patients with FT <6.5 and 76% with FT 6.5-10 complained of loss of libido as compared to 60% that had FT >10, the difference of which is statistically significant (p= 0.01).



Distribution of primary symptoms in borderline low TT patients



DISCUSSION

- Clinicians are often faced with therapeutic dilemmas in symptomatic but marginally hypogonadal patients based on TT level measurements.
- During screening, they should have not only their total testosterone levels repeated, but a FT level.
- We found that FT may help distinguish patients with sexual dysfunction symptoms and borderline total testosterone. Further study is needed to see if borderline hypogonadal patients treated with testosterone can have their sexual symptoms improved.

CONCLUSIONS

- Dilemmas exist in patients with borderline low TT as many are symptomatic as evidenced in our study.
- FT is a valuable tool to distinguish those who are symptomatic with low libido
- Insurance criteria may limit the ability of physicians to treat this group of patients, but physicians should use clinical discretion
- We propose a concept of "Relative hypogonadism" whereby treatment of this borderline group can resolve symptoms, and future study is ongoing

Reference: Tan RS. Andropause: introducing the concept of "relative hypogonadism" in aging males. Int J Impotence Research 2002; 14 (4): 319

For more information on our work on testosterone research: www.lowtinstitute.org

