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Using the ADAM Questionnaire in Primary Care to Identify Hypoandrogenism in Males Aged 40 Years or Older

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USING THE ADAM QUESTIONNAIRE IN PRIMARY CARE TO IDENTIFY
HYPOANDROGENISM IN MALES AGED 40 YEARS OR OLDER

by

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Jeremy Burns

TABLE OF CONTENTS

LIST OF FIGURES	5
ABSTRACT.....	6
STATEMENT OF THE PROBLEM	7
Background and Significance	8
ASSESSMENT.....	8
Organization’s Readiness for Change	9
PROJECT IDENTIFICATION.....	9
Purpose.....	9
Objectives	9
Anticipated Outcomes.....	10
SUMMARY AND STRENGTH OF THE EVIDENCE	10
METHODS	12
Project Intervention.....	12
Organizational Barriers, Facilitators, and Ethical Concerns.....	13
RESULTS	13
DISCUSSION.....	15
Limitations	15
Recommendations.....	16
Implications for Practice	16
REFERENCES	18

Table of Contents—Continued

APPENDIX.....21

LIST OF FIGURES

Figure	Page
1. Comorbidities of the TRT Group.....	14
2. ADAM Results before and After TRT.....	15

Abstract

Testosterone replacement therapy (TRT) has been shown to improve the symptoms of metabolic syndrome by reducing Hemoglobin A1C, belly fat, cholesterol, and blood pressure (Cunningham, 2015). The ultimate goal for testosterone-deficient patients is to have an improved quality of life by starting TRT. This quality improvement project was conducted at a small, primary care clinic in South Texas. The project was started by screening 84 male patients equal to or over 40 years of age using the Androgen Deficiency in Aging Males (ADAM) questionnaire. The ADAM questionnaire was considered positive for anyone who answered “yes” to 3 or more questions or “yes” to questions 1 or 7 (Morley et al., 2000). Out of the 84 patients screened by the ADAM questionnaire, 57 screened positive for low testosterone. Only 23 of those 57 patients agreed a confirmatory testosterone blood test; 20 of those 23 had low testosterone blood levels. Any patient who had an abnormally low testosterone level was given the option to start TRT. Eleven of the 20 patients included in the project accepted TRT. After 6 to 8 weeks of testosterone replacement therapy, patients were given the ADAM questionnaire again to assess if improved scores had occurred. After starting TRT, only 1 of the 11 participants had an unchanged ADAM score although it was noted his testosterone levels were still subtherapeutic. Ten of the 11 participants who received TRT had improved ADAM scores at the end of the project window. The ADAM questionnaire has a sensitivity of 88%-97%, so poor ADAM scores were highly linked to low total testosterone levels (Lunenfeld et al., 2015; Morley et al., 2000).

Keywords: low testosterone, metabolic syndrome, depression, erectile dysfunction, low sex drive, lack of energy, muscle loss, androgen deficiency; aging males

Baby boomers are getting older and the life expectancy of humans is increasing. This translates to primary care providers caring for more geriatric patients than their predecessors. The increased geriatric patient load leads to an increase in comorbidities that often accompany the aging population. One of those comorbidities in men is low testosterone. Although many men experience the signs of low testosterone, most assume it is a normal part of aging that does not need to be treated (Mayor, 2016). They are also misinformed on testosterone replacement therapy (TRT) (Mayor, 2016). Some providers also have misconceptions of low testosterone and TRT, so they refuse to prescribe it to their patients (Mayor, 2016).

Patients and providers must to be educated on the effects of low testosterone and its effect on the quality of life in aging males. Some of these effects include increased risk of cardiovascular disease, diabetes, depression, osteoporosis, fatigue, erectile dysfunction, decreased sex drive, loss of muscle mass, and fat gain (Cunningham, 2015; Snyder et al., 2016; Sugerman, 2013). Patients should be provided with the benefits and drawbacks of TRT in order to consider incorporating as part of their regular medication regimen. Identification of subtherapeutic testosterone levels can be facilitated by administration of the Androgen Deficiency in Aging Males (ADAM) questionnaire during routine primary care visits.

Statement of the Problem

Testosterone levels in men have been decreasing from generation to generation. The normal testosterone range in healthy men is between 300 and 1000 ng/dL; it peaks in the late 20s, but it begins to decline by 1.5% to 2% in the early 30s (Hellstrom, 2013; Travison, Araujo, O'Donnell, Kupelian, & McKinlay 2007). According to Travison et al. (2007), men have been losing testosterone, but it is not just age-related. In the same study, men aged 65 to 69 years had higher testosterone levels in 1988 (503 ng/dL) than men in the same age group in 2003 (423

ng/dL) (Travison et al., 2007). On a positive note, these men can be treated with TRT to increase their testosterone levels to a normal range.

Background and Significance

Low testosterone levels have been linked to decreased sexual function and depression (Mayo Clinic, 2019; Snyder et al., 2016). This means some men are being misdiagnosed as having depression when the etiology is low testosterone. The diagnostic criteria for depression is met but the source of the depression is improperly treated. Chronic problems such as diabetes and hyperlipidemia are also worsened by low testosterone levels (Sugerman, 2013). Men with low testosterone are also more likely to develop osteoporosis, muscle weakness, and decreased energy levels (Sugerman, 2013). This constellation of symptoms means men with a lower testosterone levels may have a lower quality of life.

TRT can reverse most of these problems. Unfortunately, it comes with some misconceptions. One myth regarding TRT is it causes an increased risk of prostate cancer. Lunenfeld et al. (2015) looked at over 3,000 patients with 6,000 controls and found no correlation between serum testosterone levels and prostate cancer. There was also no significant correlation between TRT and prostate cancer (Lunenfeld et al., 2015). In another study, Snyder et al. (2016) did note that one out of 394 patients on TRT was diagnosed with prostate cancer.

Assessment

The family practice clinical partner for this quality improvement project was located in northeast San Antonio. The clinic's patient profile comprised 50% Hispanic, 30% White, 10% Black, and 10% Other. Many of the patients often present to the clinic for depression, hyperlipidemia, hypertension, hyperglycemia, and decreased energy levels. Of the 100 random charts of men equal to or older than 40 years of age reviewed, 65 had hypertension, 91 had

hyperlipidemia, 59 had hyperglycemia and 42 had all three diagnosis. These men who visit this clinic could have a low testosterone level manifesting as the aforementioned diagnoses. The clinic did not have an assessment tool or protocol in place to query men equal to or over 40 years about symptoms traditionally associated with low testosterone.

Organization's Readiness for Change

The results of the microsystem assessment done in May 2018 were presented to the staff of the clinic to ensure understanding of the need for a testosterone screening tool. The ADAM questionnaire has a sensitivity of 88% to 97% (Lunenfeld et al., 2015; Morley et al., 2000). After presenting the results of the microsystem analysis to the staff, they agreed the ADAM questionnaire should be used to try to better identify patients with low testosterone.

Project Identification

Purpose

The purpose of this quality improvement project was to use the ADAM questionnaire as a screening tool to identify men equal to or over 40 years of age with low testosterone levels and recommend TRT when not contraindicated by personal choice or a comorbid medical condition.

Objectives

The objectives of the quality improvement project were:

1. Use the ADAM questionnaire to increase the screening of males equal to or over 40 years for low testosterone who presented to the clinic from 0% to 75%.
2. Order serum total testosterone levels on 90% of the patients identified by the ADAM questionnaire as potentially having low testosterone.
3. Offer TRT to 90% of patients who have confirmed low serum total testosterone levels.

4. Have patients started on TRT return for follow-up visit after one month to re-administer the ADAM questionnaire.
5. Improve the quality of life in males with hypoandrogenism through TRT as evidenced by an improved score in the parameters outlined in the ADAM questionnaire.

Anticipated Outcomes

By meeting the objectives of the project, the outcome was an increased identification, treatment, and management in the participants with hypoandrogenism. This may also lead to reduced Hemoglobin A1C, belly fat, cholesterol, and blood pressure among other comorbidities; however, these associated parameters were not included in the scope of this study (Cunningham, 2015). The clinic will now be able to treat patients with low testosterone according to the American Urology Association guidelines.

Summary and Strength of the Evidence

The ADAM questionnaire is a tool utilized to help identify males with low testosterone; in one study it demonstrated 88% sensitivity and 60% specificity (Morley et al., 2000). In another study, the sensitivity was 97% but the specificity was only 30% (Lunenfeld et al., 2015). The high sensitivity of these studies suggests the ADAM questionnaire may help identify males with low testosterone. Nevertheless, the low specificity makes it hard to identify those with normal total testosterone levels. Since it is not specific enough to stand alone, a blood test will be the definitive diagnostic tool used to diagnose low testosterone (Cabral, Busin, Rosito, & Koff, 2014).

There are many reasons men choose to start TRT. What can be certain is most do not know the dangers low testosterone levels have on their health. In fact, men are at higher risk for

stroke, myocardial infarction, and sudden death when they have low testosterone levels (American Urology Association, 2018). TRT has been shown to improve weight loss, libido, depression, and fatigue in men who have HIV (Hellstrom, 2013). It is plausible to reproduce similar results in men without HIV. According to Snyder et al. (2016), men treated with TRT had an increase in sexual desire, sexual function, erectile function and mood on the Psychosexual Daily Questionnaire. In fact, one study compared testosterone levels of 120 males and found patients with diabetes type 2 had a total testosterone level almost 100 ng/dL lower than patients without diabetes type 2 (Bansal, Kumar, Pathak, & Manglunia, 2017). One asks the question, “Which came first?”

Some side effects of TRT are still undetermined but there is evidence that TRT may lead to increased hemoglobin, hematocrit and prostate specific antigen (PSA) (American Urology Association, 2018). According to Lunenfeld et al. (2015), the PSA may increase over the first few months of TRT so the new baseline should be taken 6 months after TRT was started. Even with the increased PSA levels, there was no evidence of increased risk for prostate cancer (Lunenfeld et al., 2015). Several factors can affect the PSA; a urinary tract infection or prostatitis can increase it while medications used for benign prostatic hypertrophy can decrease it (National Cancer Institute, 2017). An article in *The New England Journal of Medicine* suggests periodic monitoring of prostate and cardiovascular health for men receiving TRT to ensure they do not experience any adverse effects (Swerdloff & Anawalt, 2014).

Many cardiologists are fearful about starting TRT on patients because they have read reports that TRT can have adverse cardiac effects, but the FDA has found many flaws in these reports (Cunningham, 2015). In fact, Cole et al. (2018) conducted a study with over 3,400 men aged 40 to 64 years on TRT who were either military spouses, retired military, or current military

and found they actually had a lower risk of coronary artery disease (CAD) compared to the control group $p = 0.008$. An article from the *Journal of the American College of Cardiology* examined 59 randomized control trials involving over 4,000 patients assigned to a testosterone group and over 3,000 assigned to a placebo group and found no significant difference in death from major adverse cardiovascular events including myocardial infarction or stroke (Kip et al., 2019).

Providers need to have sufficient knowledge about TRT to ensure patient safety. Lunenfeld et al. (2015) suggests using a TRT that is shorter acting in case it needs to be stopped due to side effects or adverse effects. TRT should not be started if hematocrit baseline is higher than 50% because it has been shown to increase the hematocrit (Lunenfeld et al., 2015). The risk for obstructive sleep apnea (OSA) was increased with the TRT group when compared to the control group (Cole et al., 2018). Therefore, providers should screen their patients for sleep apnea prior to starting any TRT. The patient and provider need to discuss the risks and benefits of TRT to ensure positive therapeutic outcomes. Until further research is conducted to identify the potential side effects of TRT, the ultimate decision falls on the patient.

Methods

Project Intervention

The project was conducted on male patients at least 40 years of age. Age-eligible patients presenting to a northeast San Antonio family practice clinic were administered the ADAM questionnaire in English. Once the ADAM questionnaire was completed, the provider offered further education on acquired hypoandrogenism if the patient answered “yes” to three or more questions or if he answered “yes” to question 1 or 7 (Morley et al., 2000). Every patient who screened positive on the ADAM questionnaire was offered an opportunity to have his total

testosterone blood levels drawn to confirm the diagnosis of hypoandrogenism. The patients had to have their testosterone levels drawn on two separate days in the morning when levels peaked (Sugerman, 2013). Patients also had their PSA and Hematocrit drawn before beginning TRT regimen (American Urology Association, 2018). Patients with a low total testosterone blood level below 300 ng/dl were offered TRT (American Urology Association, 2018). They were started on 1 mL of Testosterone Cypionate 200mg/mL Intramuscularly (IM) every two weeks in an effort to increase their total testosterone levels to 450-600 ng/dL (American Urology Association, 2018). After 6 to 8 weeks of TRT, the patients returned to the clinic to check their total testosterone levels. The TRT dosage was titrated base on the total testosterone results. They were also given the ADAM questionnaire to reassess symptoms. Both sets of ADAM questionnaire results were compared to identify changes associated with the administration of TRT.

Organizational Barriers, Facilitators, and Ethical Concerns

Patient records were kept at the clinic in a locked cabinet to comply with the Health Information Portability and Accountability Act. The family practice clinic partner associated with this project has previously implemented Doctor of Nursing Practice projects with great success. To ensure the regulatory and ethical compliance of this quality improvement project, the University of the Incarnate Word Institutional Review Board was consulted. The Institutional Review Board determined this project did not meet federal monitoring requirements for research involving human subjects, NRR# 18-026.

Results

The ADAM questionnaire was given to a total of 84, age-eligible males who came to the clinic in a four-week period in February and March of 2019 (Objective #1 met). The mean age of

the participants was 53 years. Of the 84 patients screened with the ADAM questionnaire, 57 screened positive for hypoandrogenism. All 57 patients who screened positive on the ADAM questionnaire were offered a total testosterone blood test to confirm the suspected diagnosis. Only 23 of those 57 patients agreed to the total testosterone blood test. Twenty of the 23 participants did have low serum testosterone levels. Objective #2 was not met as only 40% of the patients who screened positive for low testosterone agreed to have a total testosterone blood level drawn. All 20 of the patients who had a low total testosterone blood level were offered TRT, but only 11 out of the 20 decided to start TRT. Objective number three was not met because only 55% of the patients with a low total testosterone blood level agreed to begin TRT. The electronic medical records of all 11 patients were evaluated for metabolic syndrome, the results are shown in Figure 1.

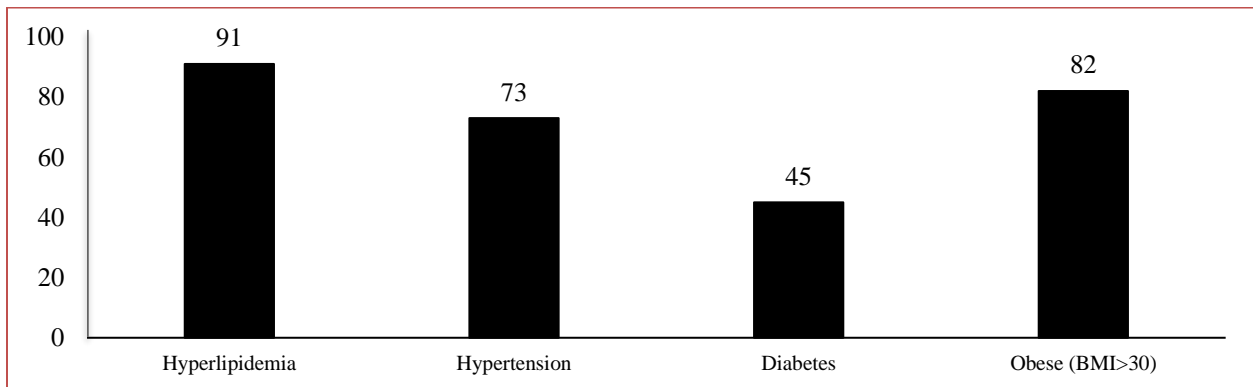


Figure 1. Comorbidities of the TRT group. The figure shows the percentage of each comorbidity found in participants during the screening for metabolic syndrome.

At four to six weeks after initiating TRT, 10 of the 11 patients returned to the clinic to have their testosterone levels drawn again (Objective #4 met). All 10 were also re-administered the ADAM questionnaire. After starting TRT, only one of the 10 participants continued with subtherapeutic serum total testosterone levels (<300 ng/dL). He also did not have any changes on

the ADAM scores. The other nine patients who were at a therapeutic testosterone level had significant improvements on the ADAM questionnaire (Objective #5 met). The differences in the ADAM scores before and after TRT can be found on Figure 2.

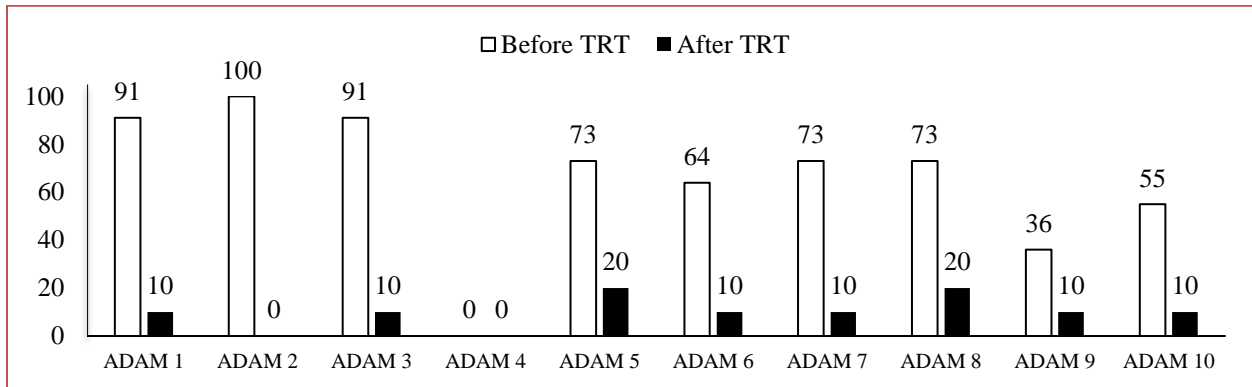


Figure 2. ADAM results before and after TRT. Percentage of patients who answered yes on the ADAM questionnaire before and after starting TRT.

Discussion

Some of the objectives were not met because many patients did not want to participate beyond filling out the ADAM questionnaire. The time limit of the project made it difficult to monitor for changes in comorbidities such as hypertension, hyperlipidemia, diabetes, and obesity. Every patient who reached therapeutic levels of testosterone had improved ADAM scores. The ADAM questionnaire proved to be a reliable tool. The sensitivity of the tool in this project was measured at 87%, close to the 88% sensitivity documented in the literature (Morley et al., 2000).

Limitations

The project had a very low sample size due to the lack of patient participation. Some men (34 out of 57) were not willing to have their blood levels drawn to see if they had low testosterone. Another challenge was 11 out of the 20 who had low testosterone levels did not

agree to start TRT. According to the research the specificity is too low to allow the ADAM questionnaire to be a stand-alone tool to diagnose low testosterone (Ugwu & Ikem, 2017). That means providers need to do a blood draw to formally diagnose patients with low testosterone. This is a problem for those patients do not have time to return to the clinic for serial blood draws.

Recommendations

The ADAM questionnaire is a good screening tool that can be incorporated in primary care settings to screen men ≥ 40 years of age for acquired hypoandrogenism. This tool will help identify men with low testosterone who are oblivious about their condition. This project also exposed the need to educate patients on the benefits and drawbacks of TRT as well as the risks of sustained low serum testosterone levels. The ADAM questionnaire is also available in many languages and it is free to use. According to the American Urology Association (2018), men should be started on testosterone if they are below 300 ng/dL and they should be brought to a therapeutic level of between 450-600 ng/dL. This suggests the American Urology Association recommends a testosterone level of at least 450 ng/dL so men who are between 300-450 ng/dL may also benefit from TRT.

Implications for Practice

The Doctor of Nursing Practice essentials were used to determine the implications for practice.

1. Scientific Underpinnings for Practice
 - A literature review was done to identify comorbidities of low testosterone.
2. Organizational and Systems Leadership for Quality Improvement and Systems Thinking
 - A systematic review of 100 electronic medical records was conducted to identify patients with the comorbidities associated with low testosterone.
3. Clinical Scholarship and Analytical Methods for Evidence-Based Practice

- Evaluated clinical site's use of any tools to identify low testosterone.
4. Information Systems / Technology and Patient Care Technology for the Improvement and Transformation of Health Care
 - Utilized the electronic medical records at the clinic to track all lab results on patients screened for low testosterone.
 5. Health Care Policy for Advocacy in Health Care
 - Implemented the use of the ADAM questionnaire to help identify men ≥ 40 with low testosterone so they could be treated with TRT.
 6. Inter-Professional Collaboration for Improving Patient and Population Health Outcomes
 - Met with all staff involved in the project to explain each individual's essential role in the project and remained available for any questions or input the staff had during the project.
 7. Clinical Prevention and Population Health for Improving the Nation's Health
 - The project was available to all male patients 40 or older who came to the clinic. All patients who screened positive for low testosterone were offered the total testosterone blood test and anyone identified with low testosterone was offered TRT.
 8. Advanced Nursing Practice
 - Mentored staff on the direction of the project to ensure the project was completed to the best of their abilities.

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Appendix

Androgen Deficiency in Aging Males (ADAM) questionnaire

Name: _____

Date of birth: _____

Today's date: _____

ADAM questionnaire includes ten questions please circle: Yes or No

1. Do you have a decrease in libido (sex drive)? Yes No
2. Do you have a lack of energy? Yes No
3. Do you have a decrease in strength and/or endurance? Yes No
4. Have you lost height? Yes No
5. Have you noticed a decreased 'enjoyment of life'? Yes No
6. Are you sad and/or grumpy? Yes No
7. Are your erections less strong? Yes No
8. Have you noted a recent deterioration in your ability to play sports? Yes No
9. Are you falling asleep after dinner? Yes No
10. Has there been a recent deterioration in your work performance? Yes No