
ANDROGEN DEPRIVATION THERAPY (ADT) OPTIONS FOR PROSTATE CANCER, SIDE-EFFECTS, & RESPECTIVE MANAGEMENT AND PREVENTION

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AGENDA

SUPPORT GROUP GOALS & GROUND-RULES

PROSTATE CANCER AND TESTOSTERONE RELATIONSHIP

WHEN TO LOWER TESTOSTERONE

HOW TO LOWER TESTOSTERONE

SIDE-EFFECTS OF LOW TESTOSTERONE

(HOT FLASHES, FATIGUE, MOOD, SEXUAL, COGNITIVE,
CARDIOVASCULAR, BONE DENSITY, WEIGHT, INSULIN RESISTANCE)

PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS

QUESTION & ANSWER



SUPPORT GROUP LONG-TERM GOALS:

Improve Shared-Decision Making

Holistically support you physical, mental, and spiritual health

Help you advocate for yourself & have confidence in your treatment plan

Help you navigate the balance of quantity and quality of life

Help decrease treatment regret, feeling overwhelmed or intimidated

Help you understand where to look for information, resources, & support



CONFIDENTIALITY & CONSIDERATIONS

Information is live streamed, not recorded

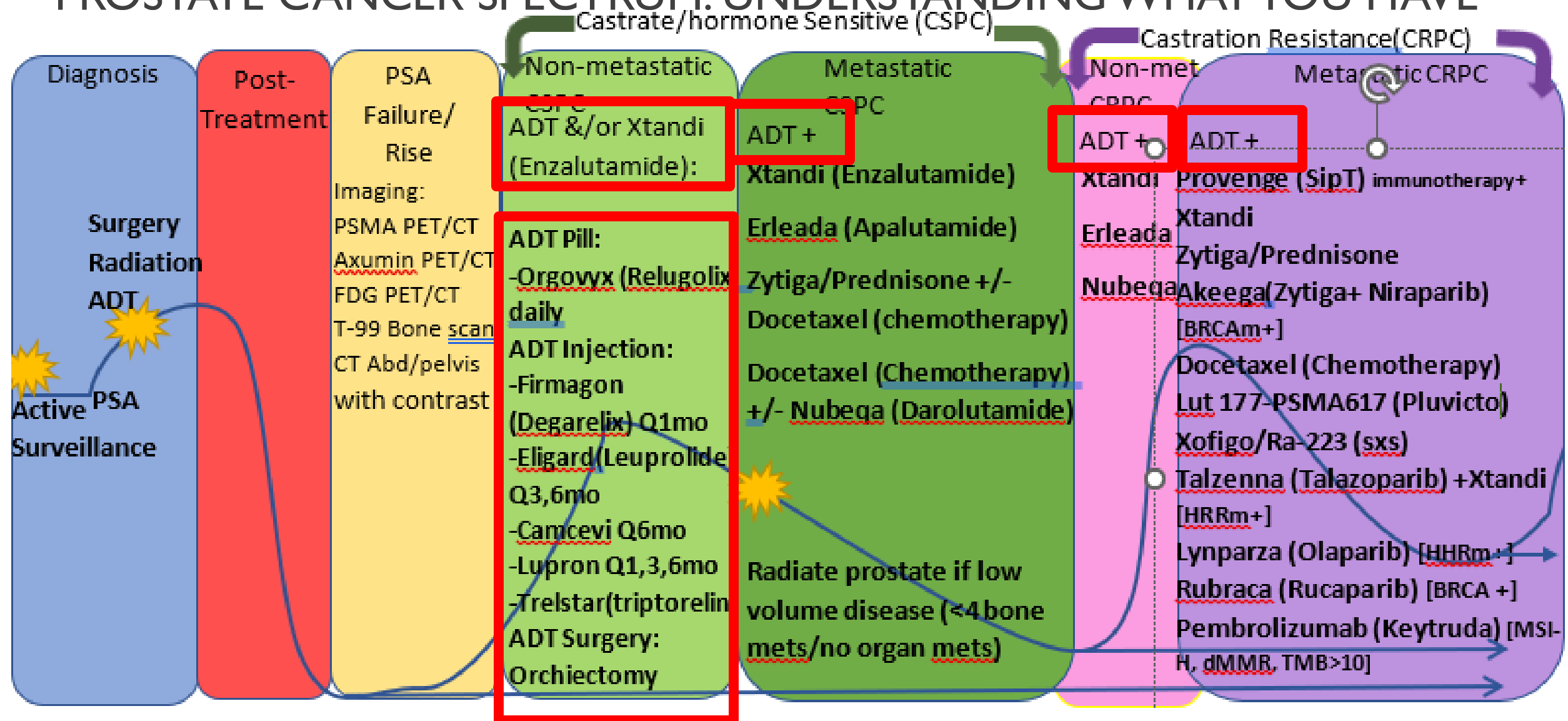
The information provided should not replace consultations with qualified health care professionals to meet your individualized medical needs

We are not here for Second Opinions but education and support

Be considerate/respectful and conscientious of others' time, feelings, and needs

Everyone is responding to their diagnosis and treatment in their own way at a different place in their prostate cancer journey

PROSTATE CANCER SPECTRUM: UNDERSTANDING WHAT YOU HAVE



YOUR TUCSON ADVANCED PROSTATE CANCER CLINIC (APCC) TEAM



Robert D. Hoy, MPAS, PA-C, DFAAPA
APC CHAMPION/RESEARCH



Jenna Hisey-Bumgardner, PA-C
APC CHAMPION



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APC CHAMPION/RESEARCH



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RADIATION ONCOLOGIST



Mina Hernandez
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GROUP COORDINATOR



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GROUP COORDINATOR



Raeshell 'Shelly' BaldeRrama, cPhT
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TUCSON CLINICAL TEAM LEAD & PROVENGE
INFUSION THERAPY PROGRAM MANAGER



Maria Webster
UUG PATIENT NAVIGATOR & PROVENGE INFUSION
THERAPY PROGRAM MANAGER



DISCLOSURES

Janssen BioTech

Dendreon

PROSTATE CANCER AND TESTOSTERONE RELATIONSHIP

- Huggins and Hodges → Paradigm shift
 - Nobel prize (1966)
 - AR highly expressed on prostate cancer cells
 - promotes survival, growth, proliferation
 - Reduced levels of androgen or blocked effect of androgen
 - disease regression



Studies on Prostatic Cancer

I. The Effect of Castration, of Estrogen and of Androgen Injection on Serum Phosphatases in Metastatic Carcinoma of the Prostate*

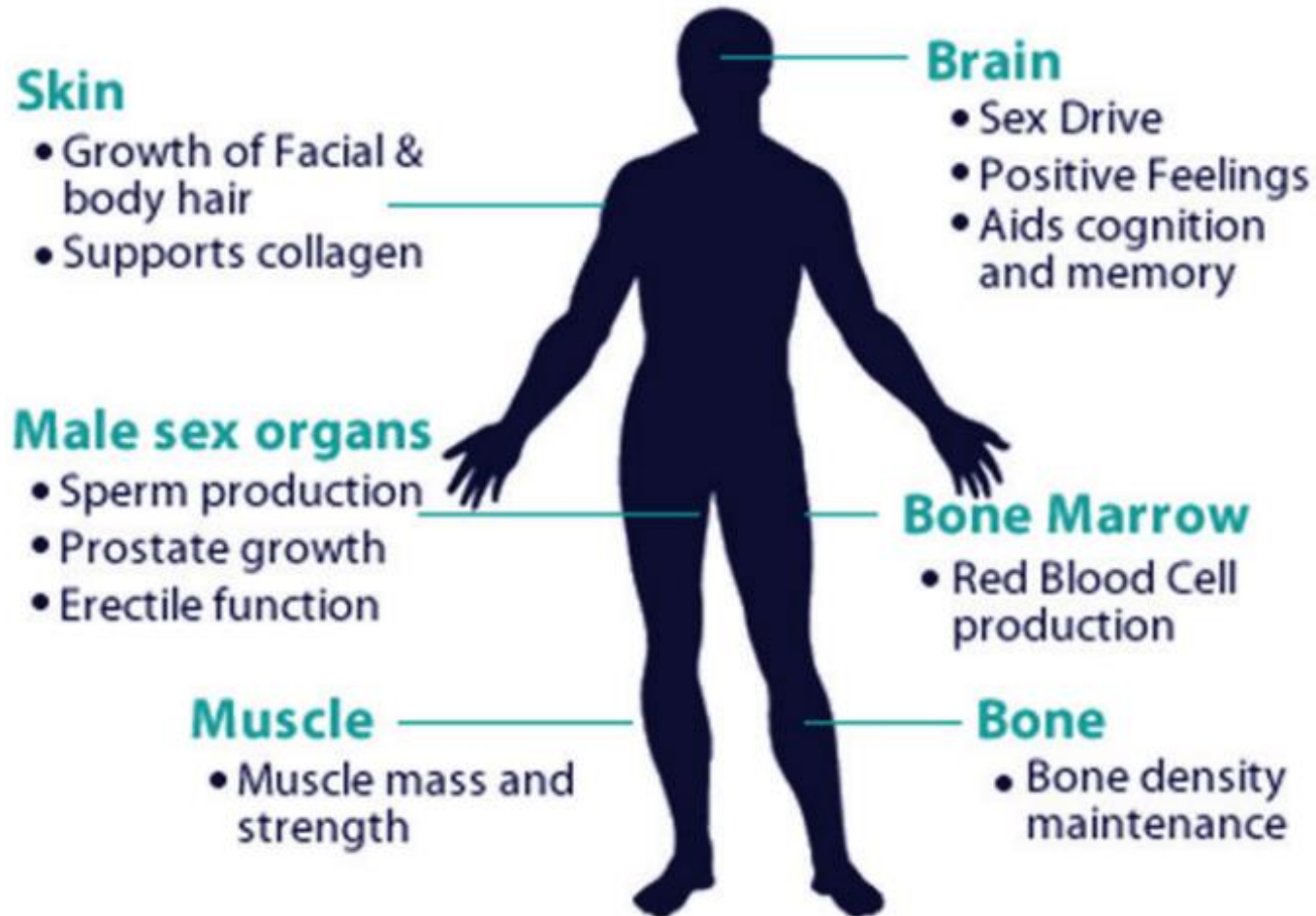
Charles Huggins, M.D., and Clarence V. Hodges, M.D.

(From the Department of Surgery, the University of Chicago, Chicago, Illinois)

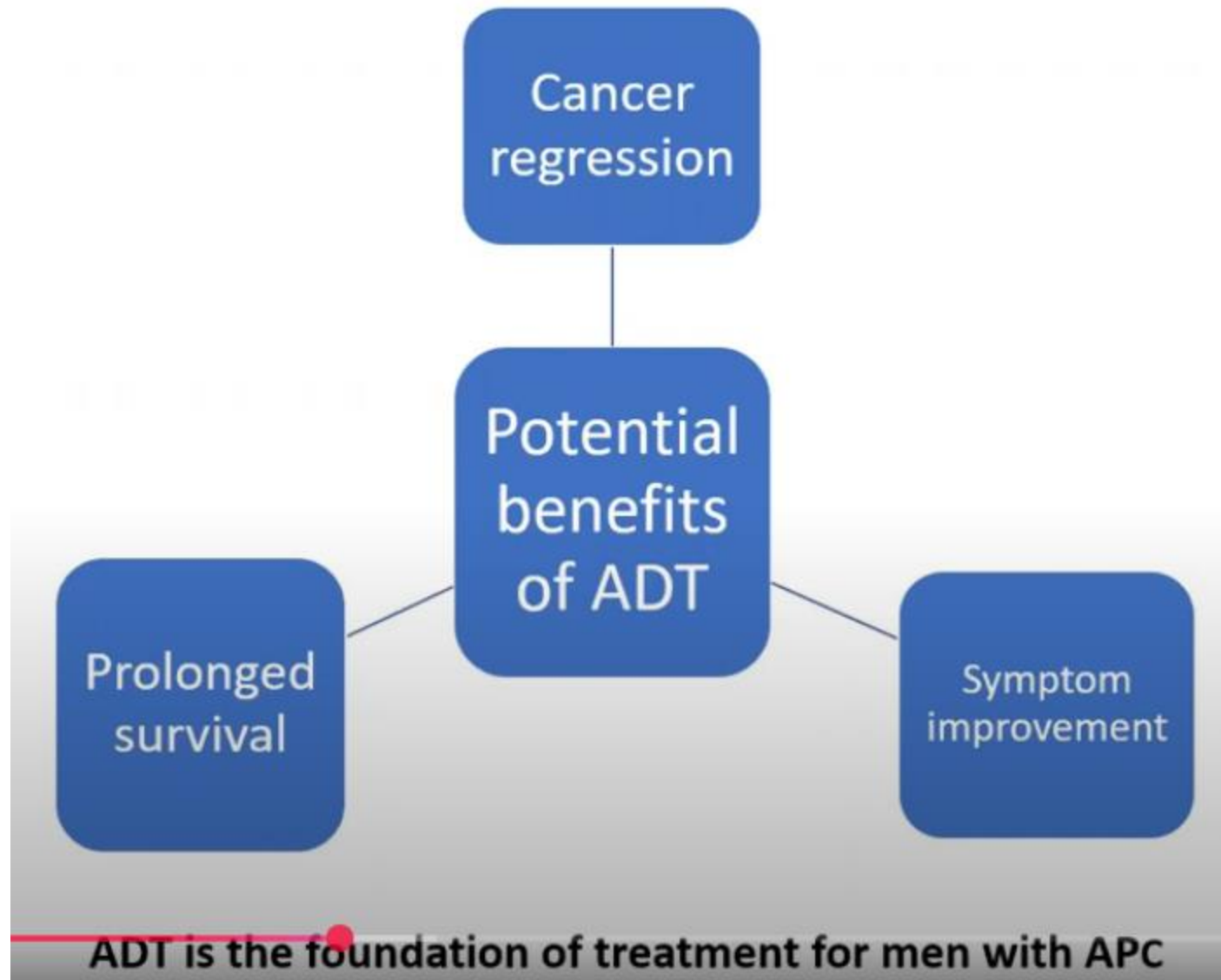
(Received for publication March 22, 1941)

PROSTATE CANCER AND TESTOSTERONE RELATIONSHIP

The Influence of Testosterone



WHEN TO LOWER TESTOSTERONE



WHEN TO LOWER TESTOSTERONE

BIOCHEMICAL RECURRENCE WITHOUT METASTATIC DISEASE

METASTATIC HORMONE SENSITIVE PROSTATE CANCER

NON-METASTATIC CASTRATION RESISTANT PROSTATE CANCER

METASTATIC CASTRATION RESISTANT PROSTATE CANCER

DISEASE STATES

Biochemical recurrence without metastatic disease

a rise in PSA in prostate cancer patients after treatment with surgery or radiation (PSA of 0.2ng/mL and a confirmatory value of 0.2ng/mL or greater following radical prostatectomy and nadir + 2.0ng/mL following radiation); this may occur in patients who do not have symptoms

Hormone-sensitive prostate cancer

prostate cancer that has either not yet been treated with ADT or is still responsive to ADT

Castration-resistant prostate cancer

disease progression despite ADT and a castrate level of testosterone (<50 ng/dL); progression may present as either a continuous rise in serum PSA levels, the progression of pre-existing or new radiographic disease, and/or clinical progression with symptoms

High volume metastatic disease

presence of visceral metastases and/or greater than or equal to four bone metastases with at least one outside of the vertebral column and pelvis

High-risk metastatic disease

disease that has a poorer prognosis in the presence of two of the three following high-risk features: Gleason ≥ 8 , ≥ 3 bone lesions, or measurable visceral metastases

De novo metastatic disease

metastatic disease that is present at the time of initial prostate cancer diagnosis rather than recurring after previous treatment of localized cancer

WHEN TO LOWER TESTOSTERONE

- Biochemical recurrence after exhausting local therapy

- What is the risk?
- How do you monitor?
- How do you manage?



Observation

Do not routinely start ADT

May offer iADT

- Newly diagnosed metastatic hormone sensitive prostate cancer

- How can you subclassify patients?
- How do you monitor?
- How do you manage?



ADT + LHRH Agonist or antagonist

ADT + Androgen pathway directed therapy or chemo

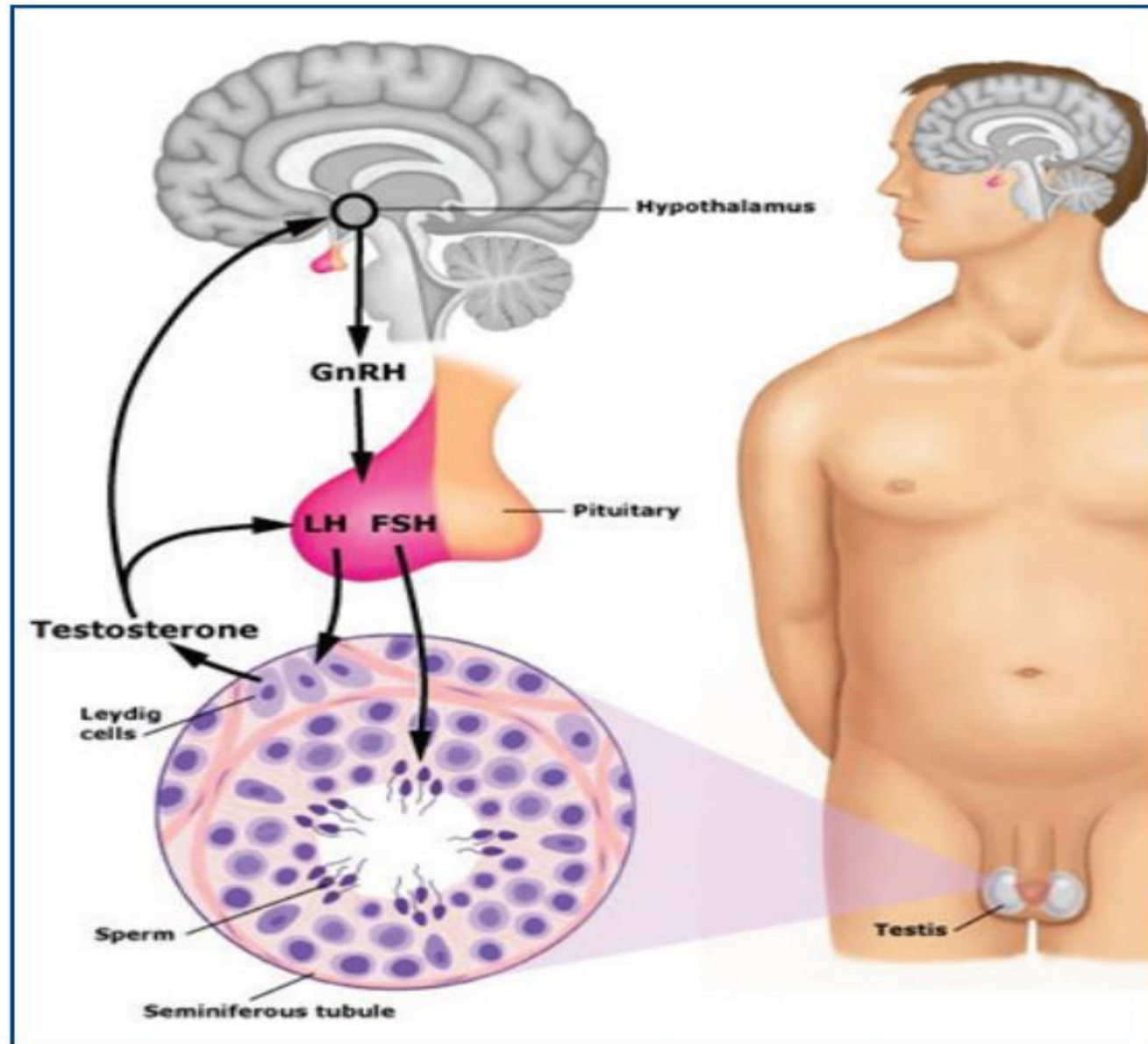
May consider XRT to primary

Treatment intensification: ADT + chemo + NHT

WHEN TO LOWER TESTOSTERONE

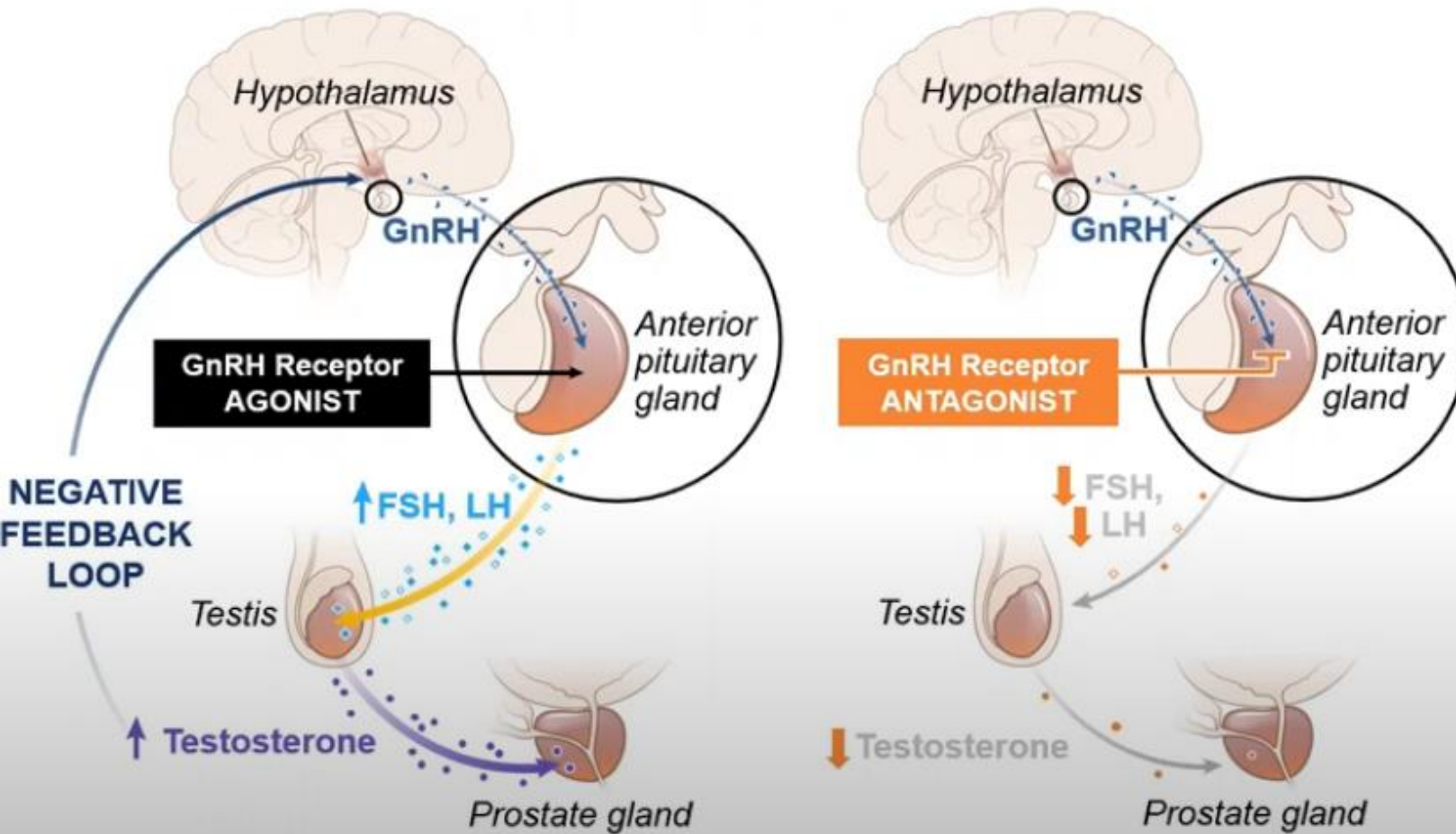
Clinical Trial(s)	Intervention	Control	Comments
STAMPEDE-H	Prostate radiation + ADT (± docetaxel)	ADT (± docetaxel)	Benefit in low-volume subgroup
GETUG-15 CHAARTED STAMPEDE-C	Docetaxel + ADT	ADT	Benefit in high-volume subgroup
LATITUDE STAMPEDE-G	Abiraterone + ADT	ADT	Similar benefits by risk group
ARCHES ENZAMET	Enzalutamide + ADT	ADT	Similar benefits by risk group
TITAN	Apalutamide + ADT	ADT	Similar benefits by risk group
ARASENS	Darolutamide + ADT + docetaxel	ADT + docetaxel	Similar OS benefit for recurrent and de novo metastatic disease
PEACE-1	Abiraterone + ADT + docetaxel (± prostate radiation)	ADT + docetaxel (± prostate radiation)	rPFS benefit for all; OS benefit in high-volume

ANDROGEN/TESTOSTERONE PRODUCTION PATHWAY



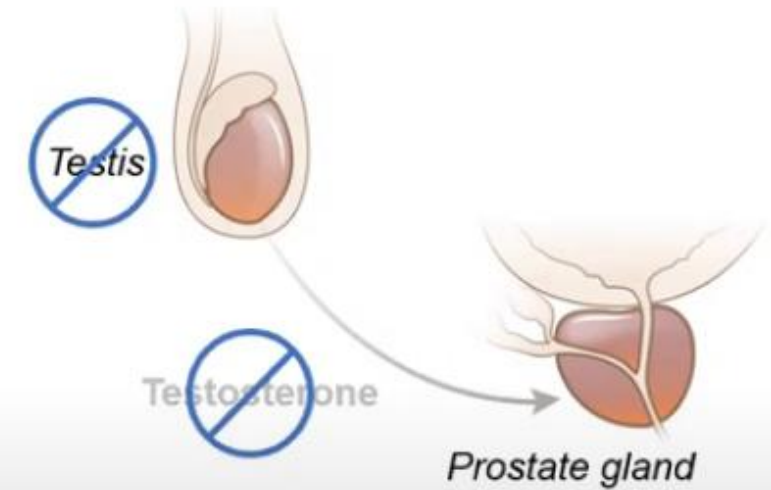
HOW TO LOWER TESTOSTERONE

Medical Castration

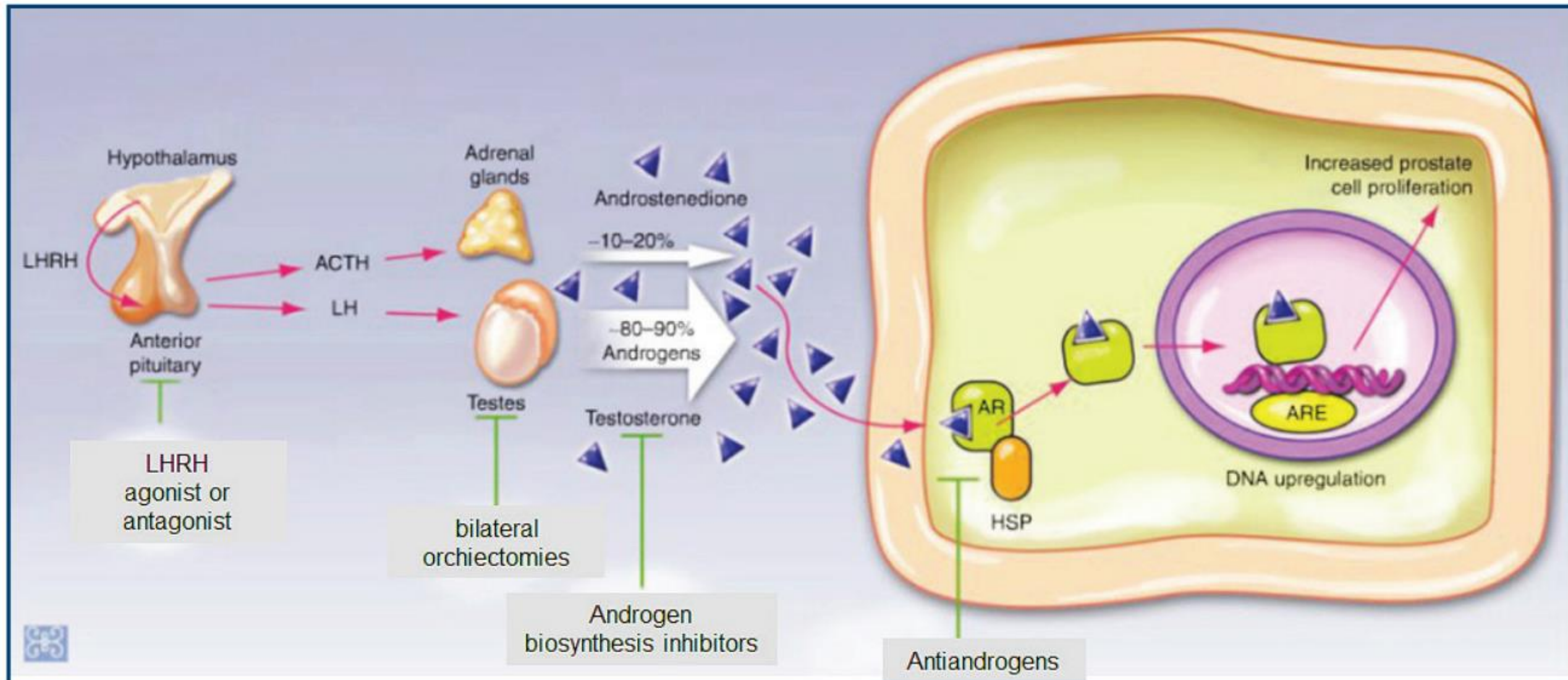


Surgical Castration

Orchiectomy



HOW TO LOWER TESTOSTERONE



HOW TO LOWER TESTOSTERONE

What is Target Testosterone Level?



Multiple guidelines
(**Bethesda
Consensus [2012],
EAU [2014], and
Canadian
Urological
Association [2018]**)
recommend T
target ≤ 20 ng/dL

FDA:

- T ≤ 50 ng/dL is the castration target and the standard for establishing efficacy
- T ≤ 20 ng/dL should be a secondary endpoint in clinical trials and data should be included in the label

AUA & NCCN
guidelines: Have
not updated

The optimal T target concentration is an ongoing subject of scientific debate but most agree lower is better

HOW TO LOWER TESTOSTERONE

Item	Antagonist	Agonist
Castrate level	96 hours	3-4 weeks
Flare	No	Yes
PSA failure	8.9%	14.1%
Local injection reaction	40%	1%
Cardiovascular complications	Conflicting data	
Administration	Monthly	Every 3 months

All GnRH agonists equally effective in cancer control. GnRH antagonists important in patients who need rapid reduction of testosterone (e.g., patients with severe symptoms or with impending emergencies – spinal-cord compression with impending paraplegia, severe bone pain or bladder outlet obstruction)





HOW TO LOWER TESTOSTERONE

Agents to treat mHSPC



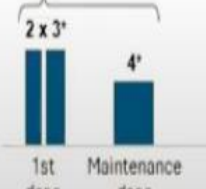
LHRH Agonist	LHRH Antagonist	Anti-androgen/AR targeted	Chemotherapy
Leuprolide	Degarelix	<u>1st Gen:</u> Bicalutamide	Docetaxel
Goserelin	Relugolix	Nilutamide	
Triptorelin		Flutamide	
		<u>2nd Gen:</u> Abiraterone	
		Enzalutamide	
		Darolutamide	
		Apalutamide	

HOW TO LOWER TESTOSTERONE

Summary Table of LHRH Therapy Options (agonists)

Attributes	leuprolide SC (Eligard [®])	leuprolide IM (Lupron [®])	triptorelin (Trelstar [®])	goserelin (Zoladex [®])
Needle Gauges	18 (45mg) 20 (7.5, 22.5, 30 mg)	23 (all doses)	21 (all doses)	16 (3.6mg) 14 (10.8mg)
Route of Administration/ Injection Angle	 SC 90° Angle	 IM 90° Angle	 IM 90° Angle	 SC 30°- 45° Angle
Dosing Intervals (months)	1 3 4 6 ✓ ✓ ✓ ✓	1 3 4 6 ✓ ✓ ✓ ✓	1 3 4 6 ✓ ✓ ✓ ✓	1 3 4 6 ✓ ✓
Injection Volume (mL)	0.25 0.375 0.50 0.375	1.0 1.5 1.5 1.5	2.0 2.0 2.0	1 cm 1.7 cm Implant (Not actual size)

Summary Table of LHRH Therapy Options (antagonists)

Attributes	degarelix (Firmagon [®])	relugolix (Orgovyx [®])
Needle Gauges	27	—
Route of Administration	 SC >45° Angle	 oral
Dosing Intervals (months)	1 3 4 6 ✓	1 st day of treatment 3 X 120 mg Then once daily 120 mg tablets*
Injection Volume (mL)	 2 x 3* 4* 1st dose Maintenance dose	—

(2x3 mL) followed by monthly Firmagon

reafford ED User Group 2017
 going to their respective owners

SIDE-EFFECTS OF LOW TESTOSTERONE



ADT Side Effects

- Sexual dysfunction
- Fatigue
- Hot flashes
- Loss of bone mineral density
- Weight gain
- Cognitive decline
- CVD
- Endocrine effects

Potential Side Effects of ADT



Bone Health



Cardiac



Sexual function



Mood and Psychological



Body image

Bell Curve



SIDE-EFFECTS OF LOW TESTOSTERONE: HOT FLASHES

Hot Flashes – 80% of men



Management can be attempted if they have a significant effect on quality of life

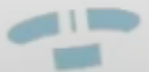


Medications

- Venlafaxine 75 mg/day
- Gabapentin 300 mg qhs (can gradually increase to TID if needed)
- Oxybutynin ?



Acupuncture



Cooling bracelet

Breast Tenderness



Prophylactic radiation to breast bud tissue if done before gynecomastia develops

SIDE-EFFECTS OF LOW TESTOSTERONE: SEXUAL DYSFUNCTION

Sexual Dysfunction – almost all men



Referral to therapist for sexual dysfunction



Lifestyle modifications

- Exercise
- Smoking cessation
- Weight loss



Medications

- Phosphodiesterase-5 inhibitors (e.g., sildenafil)

Other urologic procedures

- Vacuum Device/Pump
- Urethral Gel
- Trimix Penile injections

SIDE-EFFECTS OF LOW TESTOSTERONE: COGNITIVE

Cognition and mental health



Increased risk of dementia



Increased risk of depression and anxiety



Management

- Communicate with primary care
- Refer to social work for mental health concerns

SIDE-EFFECTS OF LOW TESTOSTERONE: FINANCIAL

Financial Toxicity



Injectables and chemotherapy are generally covered through a different benefit than oral therapies

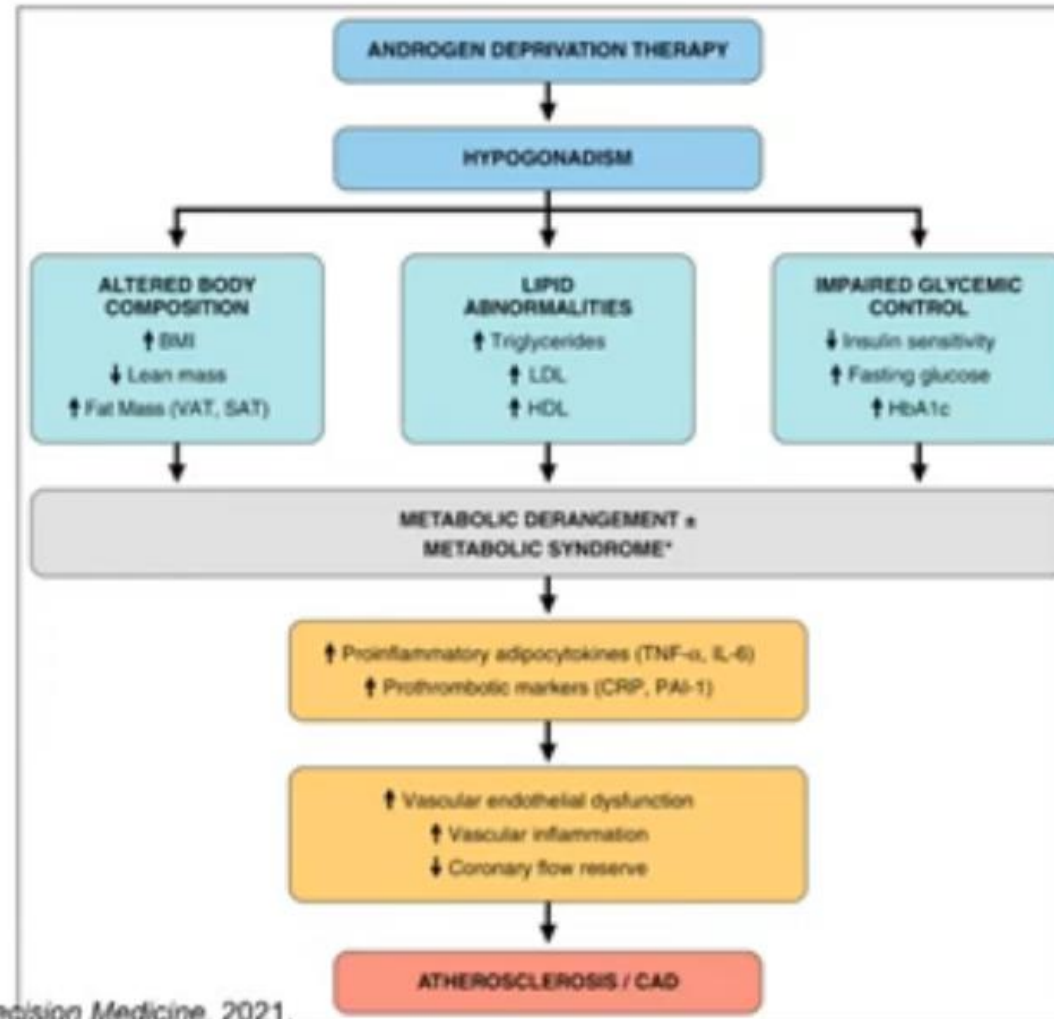


Out-of-pocket cost for oral therapies is highly dependent on insurance coverage

- For commercial insurance, there is usually a lower direct out-of-pocket cost for patients
- For Medicare Part D, out-of-pocket costs have been as high as \$10K a year for some. This will hopefully improve starting in 2024.
- Occasionally, patients with very high out-of-pocket costs will qualify for grants or free drug programs from the manufacturer.
- Don't forget the VA for Veterans

SIDE-EFFECTS OF LOW TESTOSTERONE: CARDIOVASCULAR

ADT Affects CVD Risk Factors



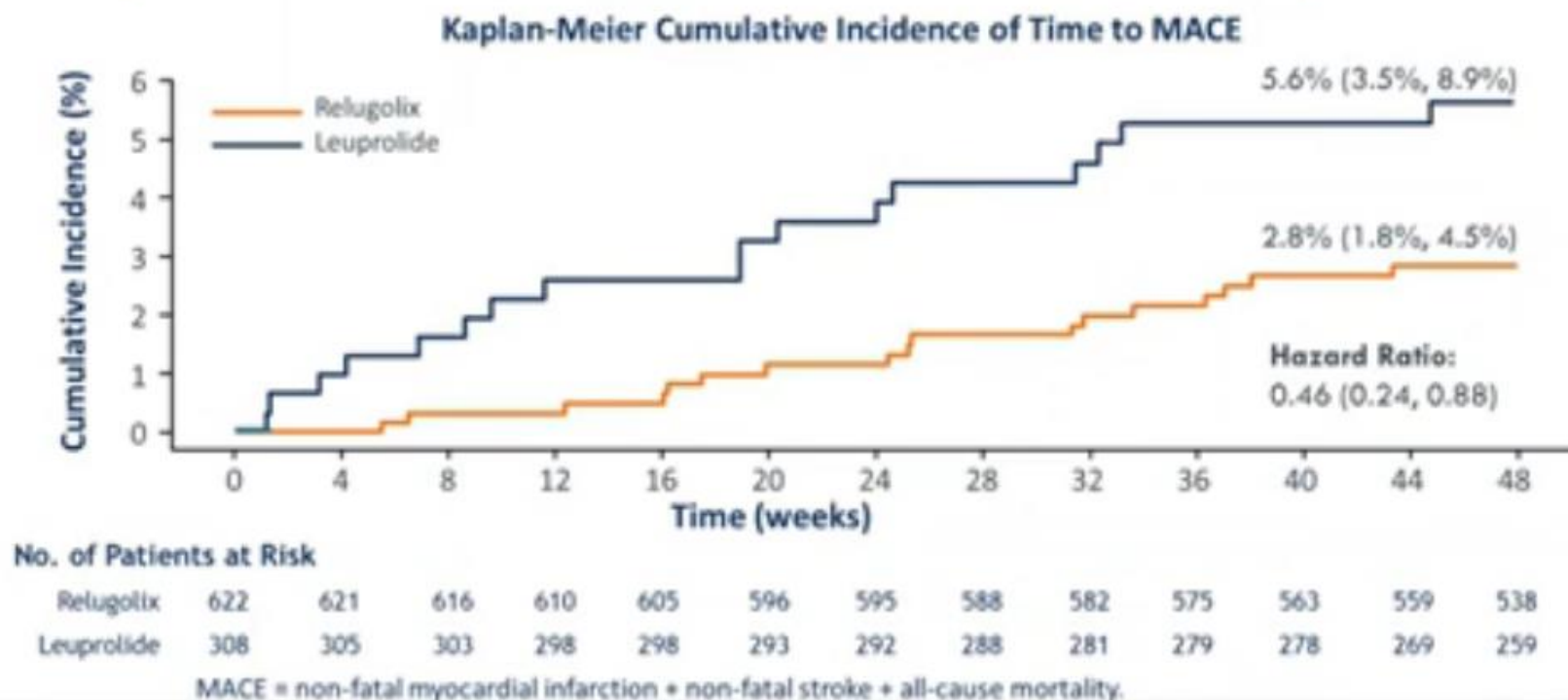
SIDE-EFFECTS OF LOW TESTOSTERONE: CARDIOVASCULAR

Cardiovascular Events in the HERO Trial



HERO

54% Reduction in Risk of
Major Adverse Cardiovascular Events (MACE)



SIDE-EFFECTS OF LOW TESTOSTERONE:WEIGHT GAIN

Abdominal Obesity and Sarcopenia during ADT



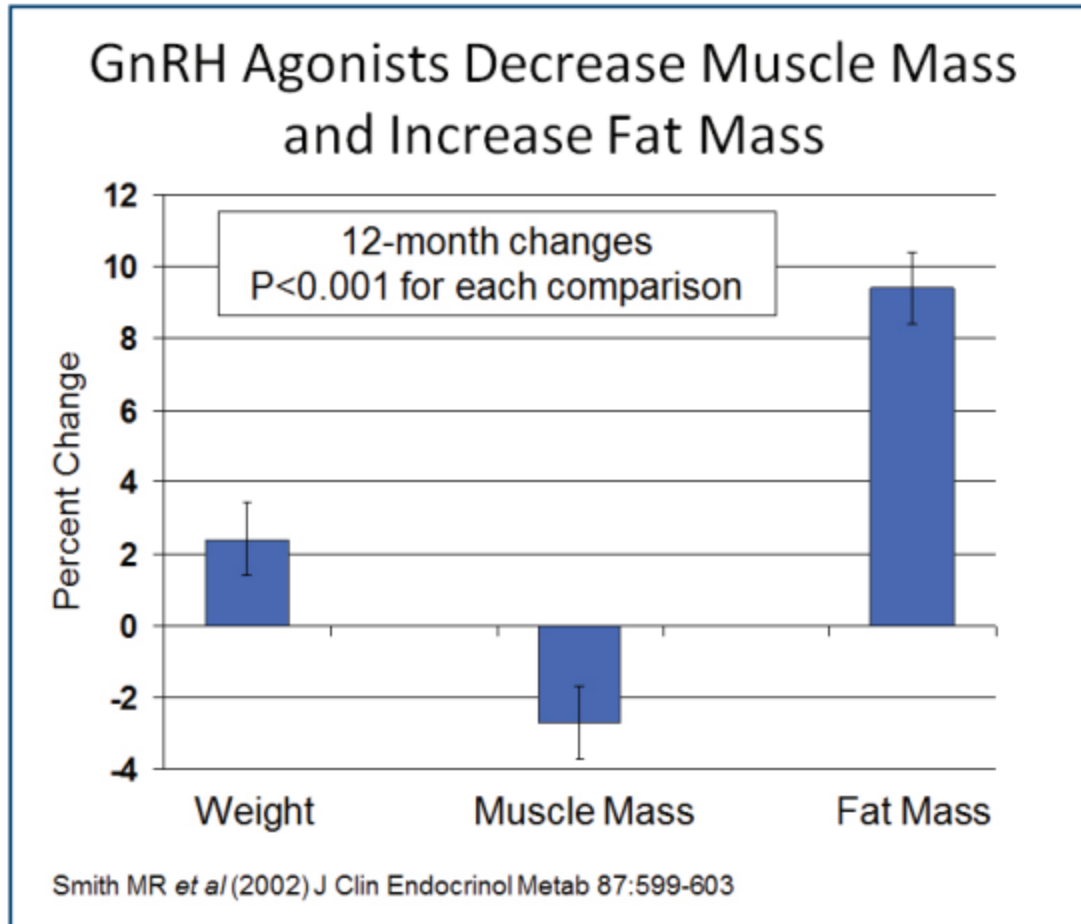
Eugonadal young man



Older man on ADT

GnRH agonist-associated sarcopenic obesity. GnRH agonists increase abdominal cross sectional area primarily through the accumulation of subcutaneous fat. Cross sectional images of a young healthy man (A) and of an obese man receiving long term GnRH agonist therapy (B). Note the relative paucity of abdominal and paraspinal musculature and the accumulation of subcutaneous fat.

SIDE-EFFECTS OF LOW TESTOSTERONE: WEIGHT GAIN



Strong evidence shows that ADT increases body weight gain and fat mass. ADT is associated with obesity-related metabolic alterations including **insulin resistance** and **increased cholesterol and triglycerides**. We recommend increased **physical activity and a plant-based diet** to prevent treatment-related obesity and associated metabolic alterations, although there is limited information about the effectiveness of these interventions during ADT.

SIDE-EFFECTS OF LOW TESTOSTERONE: BONE HEALTH

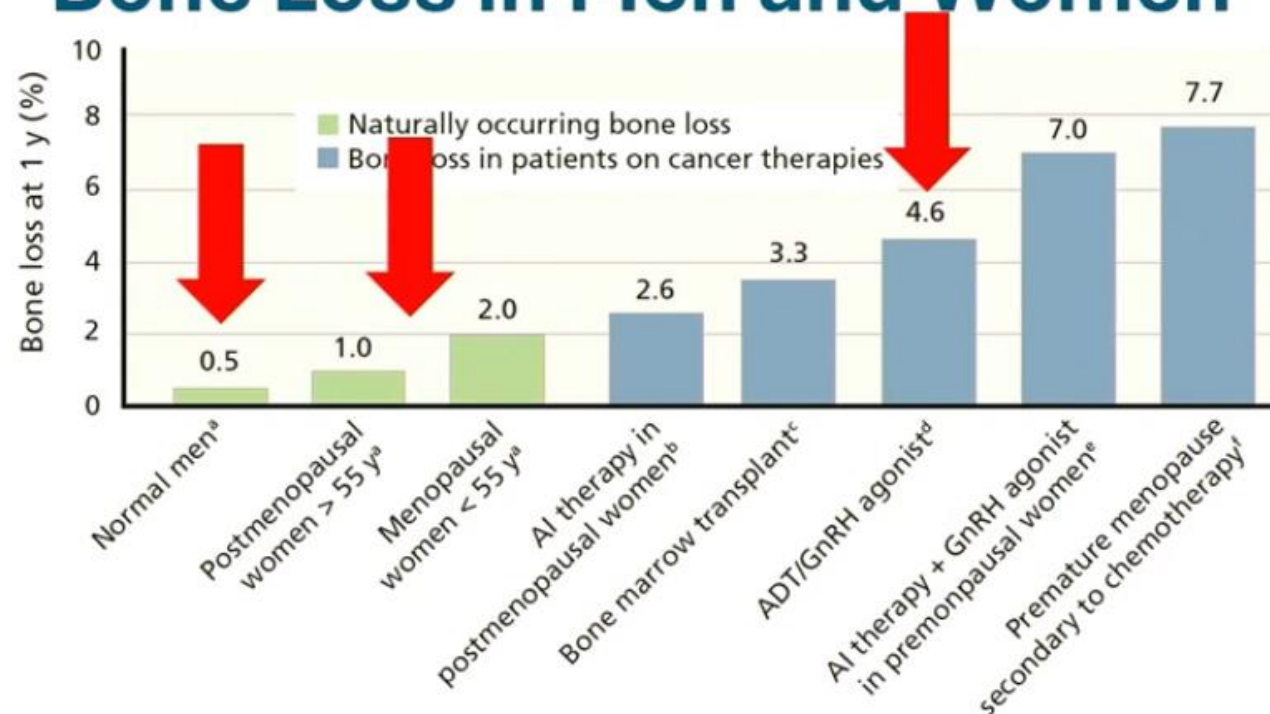
• Every second of every day, an older adult (age 65+) suffers a fall in the U.S. —making falls the leading cause of injury and injury death in this age group.

- Not only an issue for women
 - 20-25% of hip fractures occur in men worldwide
 - Mortality 2x higher for men than women in 6 months post fracture
 - Mortality persists past first year post fracture, and exceeds that of women at all time points
- Hip fracture causes
 - Loss of mobility
 - Loss of independence
 - Financial burden



SIDE-EFFECTS OF LOW TESTOSTERONE: BONE HEALTH

Rates of ADT-Induced Bone Loss vs Normal Bone Loss in Men and Women



^aRate of bone loss in the first year of ADT or AI or annualized bone loss in the general population.
ADT = androgen deprivation therapy; AI = aromatase inhibitor; BMD = bone mineral density.
1. Gralow JR, et al. *J Natl Compr Canc Netw*. 2013;11(suppl 3):s1-s50.

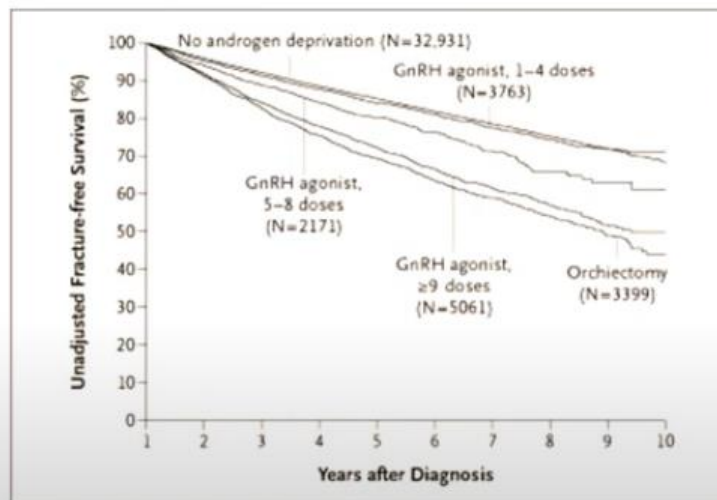
Gralow JR, Biermann JS, Farooki A, Fornier MN, Gagel RF, Kumar R, Litsas G, McKay R, Podoloff DA, Srinivas S, Van Poznak CH. NCCN Task Force Report: Bone Health In Cancer Care. *J Natl Compr Canc Netw*. 2013 Aug;11 Suppl 3:S1-S50; quiz S51. doi: 10.6004/jnccn.2013.0215. PMID: 23997241.

^bKanis JA. Pathogenesis of osteoporosis and fracture. In: Kanis JA, ed. *Osteoporosis*. London, United Kingdom: Blackwell Healthcare Communications; 1997:22-55.
^cEastell R, Hannon RA, Cuzick J, et al. Effect of anastrozole on bone density and bone turnover: results of the 'Arimidex' (anastrozole), Tamoxifen, Alone or in Combination (ATAC) study [abstract]. *J Bone Miner Res* 2002;17(Suppl 1):S165, Abstract 1170.
^dLee WY, Cho SW, Oh ES, et al. The effect of bone marrow transplantation on the osteoblastic differentiation of human bone marrow stromal cells. *J Clin Endocrinol Metab* 2002;87:329-335.
^eMaillefer JF, Sibilla J, Michel E, et al. Bone mineral density in men treated with synthetic gonadotropin-releasing hormone agonists for prostatic carcinoma. *J Urol* 1999;161:1219-1222.
^fGrant M, Jakesz R, Milneritch B, et al. Zoledronic acid effectively counteracts cancer treatment induced bone loss (CTBL) in premenopausal breast cancer patients receiving adjuvant endocrine treatment with goserelin plus anastrozole versus goserelin plus tamoxifen-bone density subprotocol results of a randomized multicenter trial (ABCSG-12) [abstract]. Presented at the 27th Annual San Antonio Breast Cancer Symposium, December 8-11, 2004; San Antonio, Texas. Abstract 6.
^gShapiro CL, Manolis J, Leffell M. Ovarian failure after adjuvant chemotherapy is associated with rapid bone loss in women with early-stage breast cancer. *J Clin Oncol* 2001;19:3306-3311.

SIDE-EFFECTS OF LOW TESTOSTERONE: BONE HEALTH

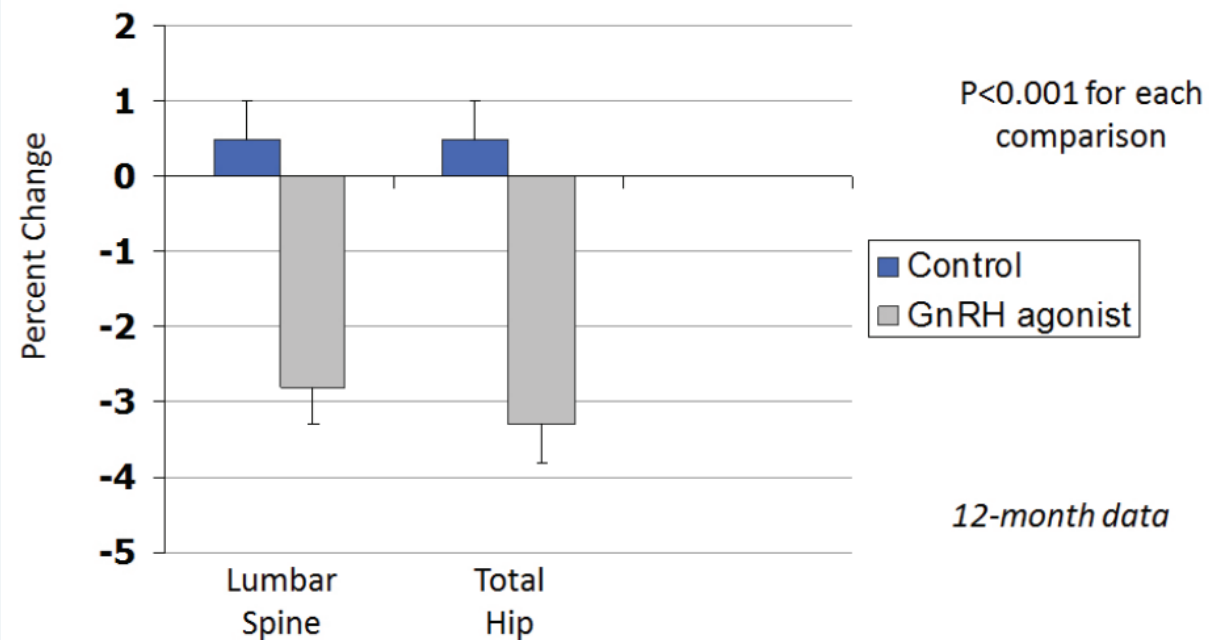
Risk of Fracture after Androgen Deprivation for Prostate Cancer

Vahakn B. Shahinian, M.D., Yong-Fang Kuo, Ph.D., Jean L. Freeman, Ph.D., and James S. Goodwin, M.D.



Shahinian VB, Kuo YF, Freeman JL, Goodwin JS. Risk of fracture after androgen deprivation for prostate cancer. *N Engl J Med*. 2005 Jan 13;352(2):154-64. doi: 10.1056/NEJMoa041943. PMID: 15647578.

ADT Decreases Bone Mineral Density (BMD) in Men with Prostate Cancer

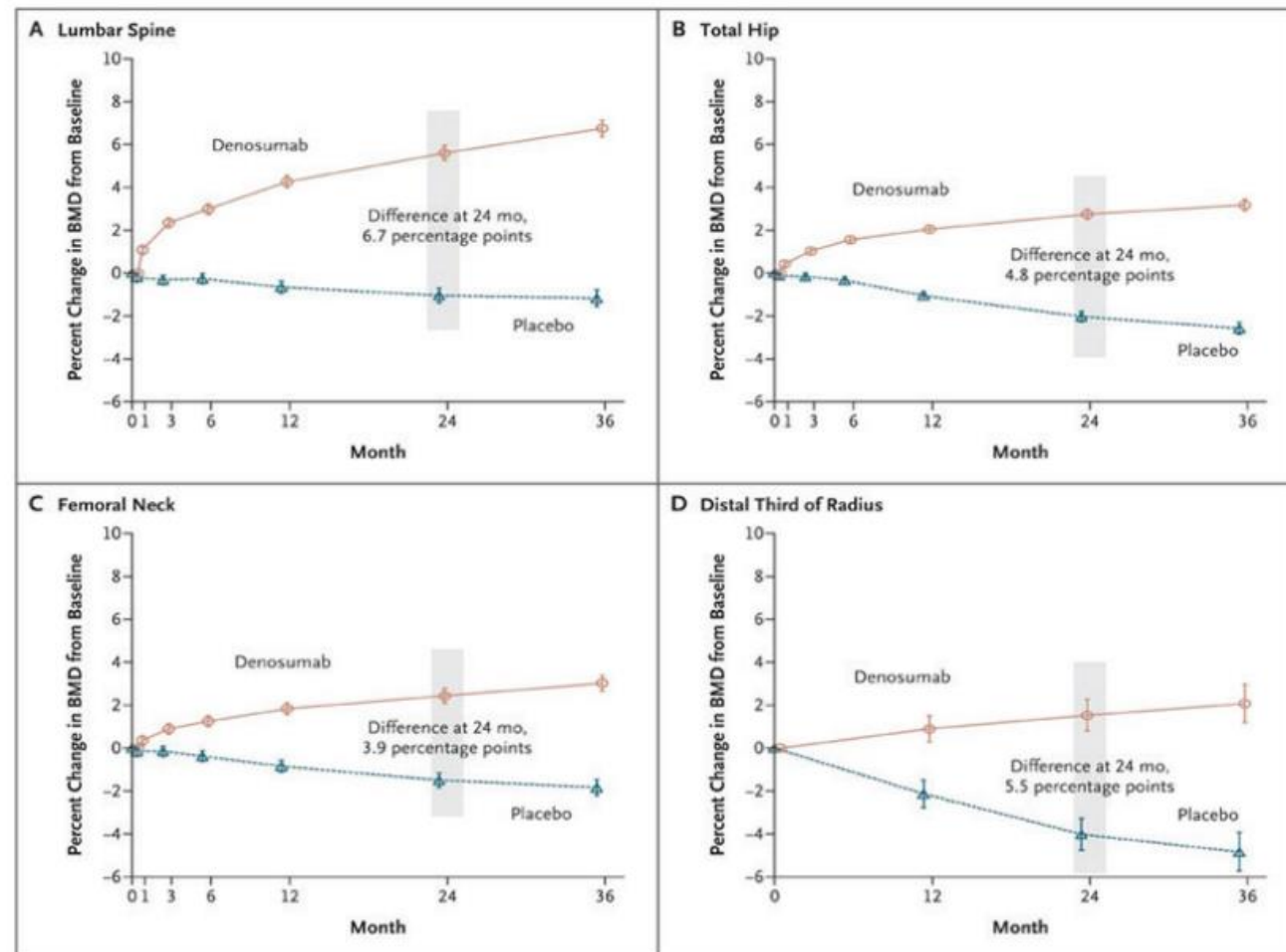


Mittan *et al* (2002) *J Clin Endocrinol Metab* 87:3656-3661

PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS

- The National Osteoporosis Foundation (NOF) recommends several interventions to reduce fracture risk in the general population.²⁵ These include an adequate intake of calcium and vitamin D, participation in **regular weight bearing** and **muscle-strengthening exercise**, **cessation of tobacco use**, identification and **treatment of alcoholism** and treatment of other risk factors for fracture such as impaired vision. NOF supports the Institute of Medicine (IOM) recommendations that men aged 50-70 consume 1,000 mg per day of calcium and **men aged 71 and older consume 1,200 mg per day of calcium**. NOF recommends an intake **of 800 to 1,000 international units (IU) of vitamin D** per day for adults aged 50 and older. The Institute of Medicine Dietary Reference Intakes for vitamin D are 600 IU per day until the age of 70 and 800 IU per day for adults aged 71 years and older.

Denosumab Increased BMD at All Skeletal Sites



Smith MR et al (2009) N Engl J Med 361:745-755

PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS: BONE HEALTH

Managing Bone Health



BONE HEALTH HISTORY

- Assess personal & family history:
 - Fragility fractures
 - Smoking history
 - Alcohol consumption



REGULAR EXERCISE

- Exercise with sufficient bone-loading force:
 - Repetitive weight-bearing aerobic (walking, aerobics)
 - Resistance training



NUTRITIONAL SUPPLEMENTATION

- Supplemental calcium and vitamin D3
- Consider anti-resorptive medications



DENSITOMETRY TESTING

- DEXA (FRAX score is an alternative)
- Baseline bone mineral density test
- Re-test every 2 years



PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS: EXERCISE

VOLUME 32 NUMBER 4 FEBRUARY 1, 2014

JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

Effects of Exercise on Treatment-Related Adverse
Effects for Patients With Prostate Cancer Receiving
Androgen-Deprivation Therapy: A Systematic Review

Jason R. Gardner, Patricia M. Livingston, and Steve F. Fraser

Improved muscle mass

Improved cardio fitness

Improved mental health

Weight loss

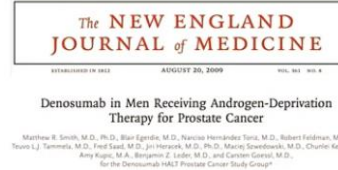
Improved strength

Decreased fatigue

Improved bone density

Improved sexual health

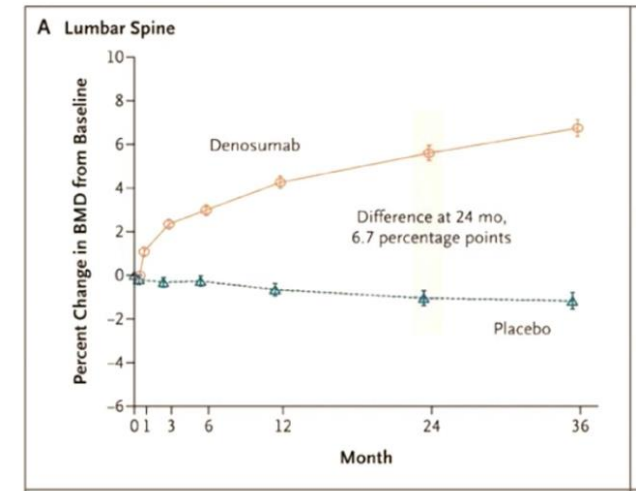
PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS



Mean Percent Changes From Baseline Bone Mineral Density (BMD) Values during the Study Period

Anti-Resorptive Therapy

- Weekly oral Alendronate
- Weekly or monthly Risendronate
- Yearly IV Zolendronic Acid
- Sub Q Denosumab every 6 months



Healthy bone



Osteoporosis

PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS: NUTRITION



PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS

Testing and Diagnosis

Osteoporosis

Age and other factors including prior fracture, smoking, alcohol use and family history of hip fracture explain most of an individual's risk for fracture. Estimate your fracture risk using the online FRAX® risk assessment tool (www.shef.ac.uk/FRAX). Bone mineral density measurement with a DXA scan may provide additional information about your fracture risk.

Obesity

Overweight/obesity is the major and most controllable risk factor for diabetes, as well as a risk factor for cardiovascular disease. Calculate your body mass index (BMI) using your measured height and weight and a BMI calculator (www.nhlbi.nih.gov/health/educational/lose_wt). BMI categories: normal weight = BMI 18.5–25 kg/m², overweight = BMI 25–29.9 kg/m² and obese = BMI >30 kg/m².

Diabetes

All men should have diabetes screening with the hemoglobin A1C blood test. Hemoglobin A1C categories: normal = A1C <5.7%, pre-diabetes = A1C 5.7–6.4%, diabetes >6.5%. If hemoglobin A1C is normal, repeat testing at least every 3 years.

Cardiovascular Disease

The major controllable risk factors for cardiovascular disease are high blood pressure, high LDL cholesterol and smoking. All men should have screening for high blood pressure and cholesterol. Blood tests for cholesterol should be performed at least every five years.

Healthy Lifestyle

Lifestyle changes that promote general health may also reduce your risks for adverse effects of ADT.

Healthy Habits

- Stop tobacco use
- Limit alcohol intake

Healthy Nutrition

- Increase consumption of vegetables and fruits, including calcium-rich plants
- For overweight and obese men, start a support program targeting 7% weight loss

Exercise

- Increase physical activity to at least 150 minutes per week of moderate activity to prevent/treat obesity and reduce risks for diabetes and cardiovascular disease
- Increase weight bearing exercise to reduce fracture risk
- Resistance exercise training may prevent muscle loss

See PCF Monograph entitled “*Health and Wellness: Living with Prostate Cancer*” for additional diet and lifestyle recommendations. (www.pcf.org/guides)

Supplements and Medications

- Vitamin D 600–1,000 IU daily to prevent bone loss
- For men with prior history of fracture, osteoporosis or an elevated fracture risk based on FRAX, consider treatment with a marketed drug to prevent fractures.
- Statins are the mainstay of treatment for elevated cholesterol.

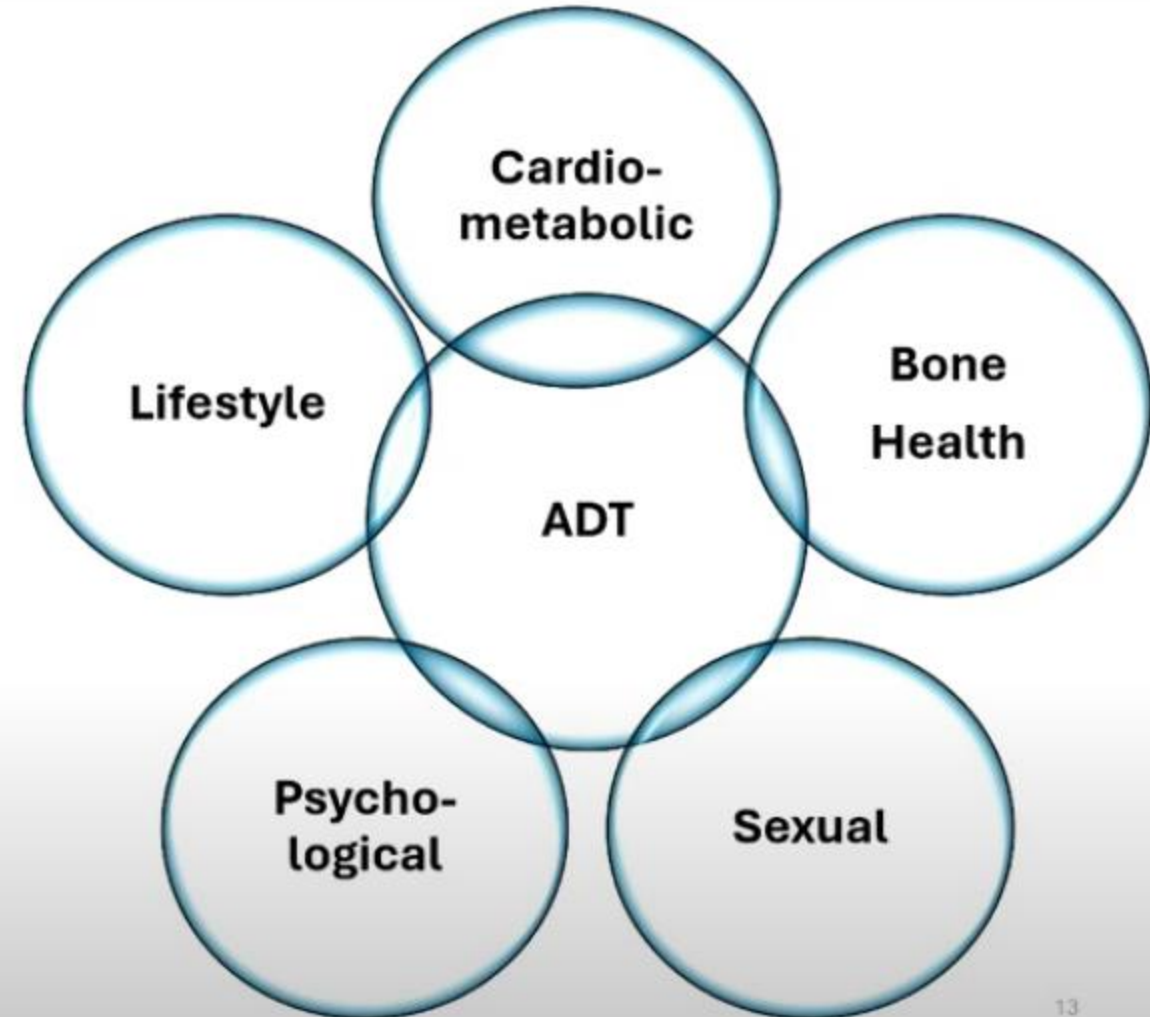
PREVENTION AND MANAGEMENT OF LOW TESTOSTERONE SIDE-EFFECTS

A multidisciplinary approach may help to medically optimize and closely observe patients before and during treatment with ADT.

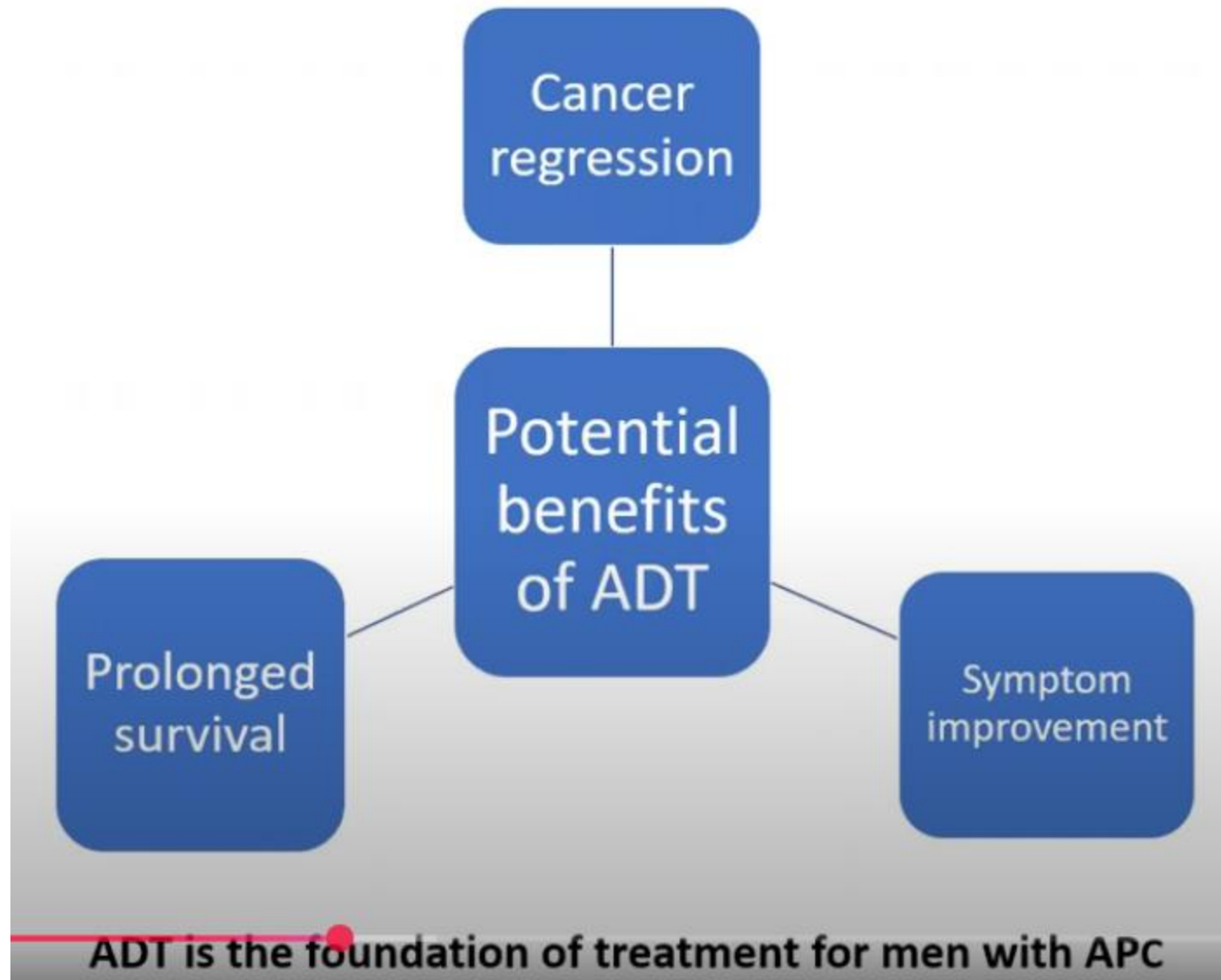
- Consider referral to cardiologist for patients with pre-existing CVD
- Consider referral to primary care provider for periodic follow-up evaluation including assessment of blood pressure, lipid profile, and glucose level

Understanding the Complications of ADT is Critical to Optimizing Health Outcomes

Patients need primary care and cancer care providers to work together to prevent ADT complications



WHEN TO LOWER TESTOSTERONE





QUESTION & ANSWER



JOIN US FOR THE NEXT SUPPORT GROUP (SUBJECT TO CHANGE)

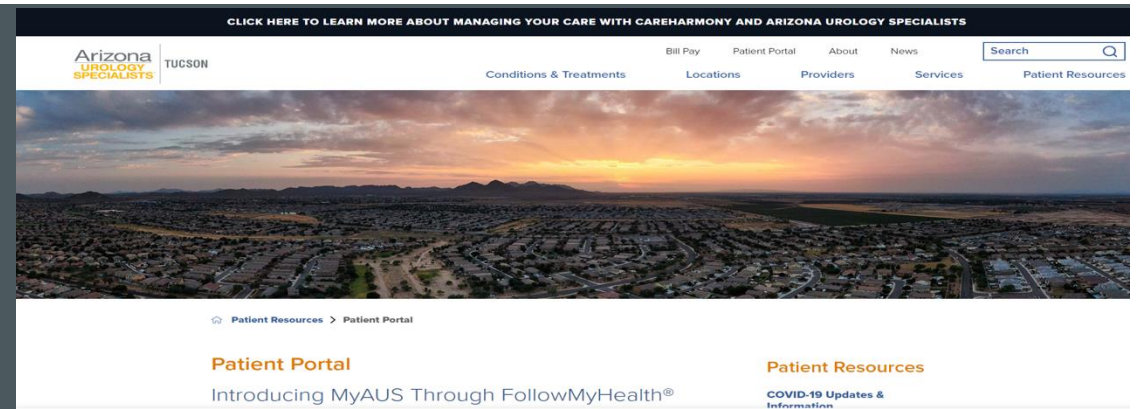
- ~~May 2024: Intro to Prostate Cancer: Risk factors, screening, biomarkers, staging, imaging~~
- ~~Aug 2024: Stress Management & Self-Care with prostate cancer or terminal cancer~~
- ~~Nov 2024: Urinary Leakage & Pelvic Floor Therapy~~
- ~~Feb 2025: Testosterone Lowering treatments & side-effect management~~
- **May 2025: Stigma & Myths vs benefits of Chemotherapy/Palliative/Hospice care**
- Aug 2025: Erection Treatments
- Nov 2025: Financial Toxicity & Resources
- Feb 2026: The Immune System and Prostate Cancer



PLEASE COMPLETE THE SURVEY AND
LET US KNOW HOW WE ARE DOING

THANK YOU, WE ARE HERE
FOR YOU!

<https://www.unitedurology.com/arizona-urology-specialists-tucson/patient-resources/patient-portal/>



Gender	Percentage
Male	55%
Female	45%

- AUA University Jan 24 2023: Advanced in ADT: A Guide for Urologists & APPs. Course Director: Kristen Scarpato, MD
- https://www.pcf.org/wp-content/uploads/2016/10/MaintainingHealthADT_Monograph_2017.pdf
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