

HPGA Normalization Protocol After Androgen Treatment

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Objective

To develop an approach to cycle androgens that would result in significant changes in body composition and accelerate the normalization of the hypothalamic pituitary gonadal axis (HPGA) after cessation of androgens.

Methods

An uncontrolled study of 19 HIV-negative eugonadal men, ages 23 – 57 years, administered testosterone cypionate and nandrolone decanoate for 12 weeks, and then were treated simultaneously with a combined regimen of human chorionic gonadotropin (hCG) (2500 IU/QODx16d), clomiphene citrate (50 mg PO BID x 30d) and tamoxifen (20 mg PO QD x 45d), to restore the HPGA.

Results

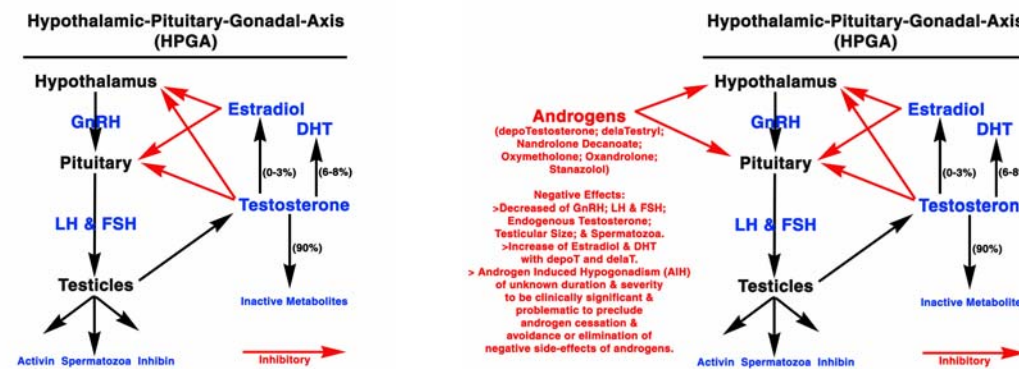
Mean FFM by DEXA increased from 64.1 to 69.8 kg (p<.001); percent body fat decreased from 23.6 to 20.9 (p<.01); strength increased significantly from 357.4 lb to 406.4 lb (p=.02). No significant changes in serum chemistries and liver function tests were found. HDL-C decreased from a mean value of 44.3 to 38.0 (p=.02). Mean values for luteinizing hormone (LH) and total testosterone (T) were 4.5 and 460, respectively prior to androgen treatment. At the conclusion of the 12-week treatment with androgens the mean LH <0.7 (p<.001) and total testosterone was 1568 (p<.001). The mean values after treatment with the combined regimen were LH=6.2 and testosterone=458.

Discussion

The use of androgens has been reported to improve lean body mass, strength, sexual function, and mood accompanied by side effects caused by continuous uninterrupted use of these compounds (polycythemia, testicular atrophy, hypertension, liver dysfunction [oral androgens] and alopecia.) Androgen-induced HPGA suppression causes a severe hypogonadal state in most patients that often require an extensive period of considerable duration for normalization. This prevents most if not all individuals from cycling off these medications due to the adverse impact of this state on their previously gained LBM and quality of life. The protocol of hCG-clomiphene-tamoxifen was successful in restoring the HPGA within 45 days after androgen cessation. Further controlled studies are needed to determine if these results can be duplicated in HIV-positive subjects.

Patient General Characteristics			
	Mean	SD	Range
Age (yrs)	36.4	9.6	23-57
Height (cm)	179.3	10.3	152.4-198.1
Weight (kg)	87.7	9.8	71.7-106.6
BMI (kg/m ²)	27.5	4.7	22.3-42.8

Serum Chemistry							
	Initial		Final		Change		P
	Mean	SD	Mean	SD	Mean	SD	
BUN	20.1	5.5	20.7	6.2	0.6	0.7	NS
ALKP	75.8	15.4	65.6	20.1	10.2	4.8	.005
ALT	37.1	23.9	42.3	35.9	5.2	12.0	NS
AST	32.8	14.4	38.9	25.7	6.1	11.4	NS
Chol, Total	191.2	45.5	185.3	39.5	5.9	6.0	NS
HDL-C	44.3	14.1	38.0	11.2	6.3	2.9	.02
LDL-C	114.7	38.1	112.0	39.1	1.8	1.1	NS
TG	165.8	119.6	169.5	98.9	3.6	20.7	NS



Medline Literature Search	
HPGA Normalization Studies For Androgens (Type, Dose, & Duration).	0
Medical Protocols/Interventions For HPGA Normalization.	0
Androgen Cycles Effecting Positive Body Composition Changes Combined w/ HPGA Normalization.	0
Medical Interventions To Eliminate/Minimize Adverse Side-Effects During Androgen Cycles.	0
Prevalence of Androgen Induced Hypogonadism Rx'ed w/ Testosterone ...	

Mean Hormone Levels During Program											
	Initial		Day 30		Day 90		Final		Change		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
T	459.5	224.4	1568.0*	551.6	1262.9*	551.6	457.9	206.7	-1.6	17.7	NS
LH	4.5	1.9	<0.7*	-	<0.7*	-	6.2	5.5	1.7	3.6	NS

* P<.001 to initial value.

Mean Body Composition & Strength							
	Initial		Final		Change		P
	Mean	SD	Mean	SD	Mean	SD	
Fat (%)	23.6	7.2	20.9	4.8	2.8	2.4	.02
Weight (kg)	87.7	9.8	91.5	9.2	3.8	0.6	.001
Fat Free Mass (kg)	64.1	7.3	69.8	7.7	5.7	0.3	.001
Fat (kg)	23.4	7.0	21.6	5.0	1.9	1.9	NS
Σ Strength Tests (3)	357.4	125.6	406.4	151.4	49.0	25.9	.05