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Effects of Cross-Sex Hormone Treatment on Transgender Women and Men

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Abstract

Objectives—To describe weight, body mass index, blood pressure, lipids, and hormone levels in transgender women and men presenting for initiation of cross-sex hormone therapy at a community clinic in the United States.

Methods—Twenty three transgender women (persons assigned male at birth who identify as women and want to use estrogen to develop female secondary sex characteristics) and 34 transgender men (persons assigned female at birth who identify as women and want to use testosterone to develop male secondary sex characteristics) presenting for initiation of hormone therapy at a community health center were enrolled. Body mass index, blood pressure, lipids, and sex hormone levels were measured at baseline and 6 months. Persistence of menses at 6 months in transgender men was recorded.

Results—Sixteen transgender women and 31 transgender men completed the study. Baseline and 6 month median blood pressures and lipid values were within a normal clinical range. Median systolic blood pressure in transgender women dropped from baseline 130.5 mmHg (IQR 11.5) to 120.5 mmHg (IQR 15.5) at 6 months ($p=.006$). Testosterone levels remained elevated in 33% and estradiol levels were supratherapeutic in 19% of transgender women at 6 months. Median body mass index for transgender men was 29.1 kg/m² (IQR 11.2) at baseline and 30.0 kg/m² (IQR 11.4) at 6 months ($p=.024$). Six month total testosterone levels were subtherapeutic in 32% and estradiol levels remained elevated in 71% of transgender men.

Conclusions—In transgender women, estrogen therapy, with or without anti-androgen therapy, was associated with lower blood pressure. In transgender men, testosterone therapy was associated with increased body mass index. The study had insufficient power to detect other associations. Monitoring of hormone levels to guide therapy appears to be useful.

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Introduction

Transgender persons commonly undergo cross-sex hormone therapy. Transgender women are persons assigned male at birth, but who identify as women and who want to use estrogens with or without an anti-androgen to develop female secondary sex characteristics. Transgender men are persons assigned female at birth but who identify as men and want to use testosterone to develop male secondary sex characteristics. (1) Existing data on the effects of these hormones lipids, blood pressure (BP), and body mass index are mostly limited to retrospective European cohorts. (2,3,4) Guidelines for dosing and monitoring have been published however most are based on expert opinion and extrapolations from related disciplines such as menopausal hormone therapy. (5,6) Recommendations for monitoring hormone levels are not based on solid evidence. Furthermore, funding opportunities in the United States for biomedical research on transgender persons outside of the HIV arena have been scant. (7) This combination of factors underlies the lack of prospective biomedical studies on hormone therapy administration and related health effects.

In contrast to Europe, where most transgender care is centralized at nationally sanctioned and academically oriented gender centers, transgender care in the United States often occurs in a patchwork of community clinics with limited research infrastructure. Given this it is likely that the development of longitudinal cohorts of transgender people in the US will involve community based clinics rather than referral center consortia. The feasibility of such research in this very unique population has not been tested.

The primary aim of this study was to describe blood pressure, lipids, body mass index, estradiol, and free and total testosterone levels at baseline and after 6 months of cross-sex hormone therapy in a community based sample of transgender patients in the United States. The secondary aim was to examine the feasibility of such a study in a community-academic partnership.

Materials and Methods

The study site is a large lesbian, gay, bisexual and transgender (LGBT) community health center located in Los Angeles, CA with a regionally well-known transgender health program; at the time of the study the health center had an average transgender patient census of >500. The clinic is a Federally Qualified Health Center and part of the healthcare safety net system. The site has existing basic research infrastructure but had not previously engaged in biomedical research on transgender patients. A collaborative study team was assembled with investigators from the study site, two academic institutions, and from a local community clinic consortium. Research methods were reviewed and approved by the Institutional Review Board at Children's Hospital – Los Angeles. Inclusion criteria were self-identified as transgender and presenting for initiation of hormone therapy, no prior use of hormone therapy by self-report, no contraindications to hormone therapy, ability to read and write in English and stated ability to adhere to the study regimen and schedule.

Subjects were recruited from a consecutive sample of patients presenting for initiation of hormone therapy between September 1, 2012 and April 1st, 2013 using an informed consent

protocol. (8) Sample size was determined by the number of patients presenting during the enrollment period who met inclusion criteria and agreed to participate, up to a planned maximum of 75 subjects due to funding limitations. Potential subjects were offered enrollment upon arrival for their scheduled new patient appointment. Subjects underwent verbal and written consent by a research assistant after which they were seen by the study clinician. Office visit procedures and frequency, treatment regimens, lab draw process and frequency were identical to those used for non-study patients treated at the clinic.

Subjects were treated following evidence based practices and were permitted to choose from various appropriate hormone regimens based on their preference and provider judgment.

Transgender women were treated with estrogens. Fourteen (88%) were given sublingual micronized 17-beta estradiol 2 mg twice daily. One subject was given 100 mcg estradiol via transdermal patch, and one subject received estradiol valerate 20 mg intramuscular every 2 weeks. All but one transgender woman (who wished to retain erectile function) were administered spironolactone; all were started on 50mg twice daily dosing; 10/15 (66%) had doses increased to 100 mg twice daily at the three month mark.

Transgender men were treated with testosterone. All but three (90%) were given weekly subcutaneous testosterone cypionate 200 mg/ml concentration, starting at 50 mg/wk; 10 subjects were increased to 70 mg/wk at the three month mark due to persistent menses. Of the three transgender men not choosing injected testosterone, two used 5g/day of 1% testosterone gel, and one used 4mg/day of a testosterone transdermal patch.

Hormone regimens offered to patients were adapted from available published evidence. Regimens from the 2009 Endocrine Society Clinical Practice Guidelines were used as a basis with two modifications. Those subjects choosing oral estradiol were instead instructed to administer the medication via sublingual route. This route has a theoretical reduction in hepatic first pass metabolism and is believed by some experts to reduce thromboembolic risk, while maintaining similar drug action. (18,19) Injected testosterone was administered via subcutaneous route, which permits the use of a smaller needle. Subcutaneous administration is gaining popularity among some experts and two small studies have suggested noninferiority to the intramuscular route. (20,21)

Subjects were given a \$25 Visa gift card at the completion of the intake visit and drawing of baseline labwork, and another \$25 gift card at the completion of the 6 month visit and labwork. Data were collected into an electronic medical record and then abstracted into Microsoft Excel. Statistical analysis was conducted using Excel and Stata IC-12. Due to non-normal distribution of results, median and interquartile range were reported and non-parametric analyses were conducted using the Wilcoxon-Signed-Rank test, Chi-square test Fisher's exact test, McNemar's test, and Spearman correlation coefficient; a p-value of <0.05 was defined as statistically significant.

Age, gender identity, birth sex, race and ethnicity were collected at baseline. Height (cm), weight (kg) and blood pressure (mm Hg) were collected at baseline and 6 month visits by a trained medical assistant using standardized techniques. Baseline and 6 month serum fasting lab studies were performed by the Laboratory Corporation of America (LabCorp,

Burlington, NC) and included serum high density lipoprotein, total cholesterol, and triglycerides by enzymatic assay, serum total estradiol (female reference range 12.5–498 pg/dl; male reference range 7.6–42.6 pg/dl) and total testosterone (female reference range 8–48 ng/dl; male reference range 348–1197 ng/dl) by electrochemiluminescence immunoassay, and serum free testosterone (female reference range 0.0–2.2 ng/dl; male reference range 8.6–26.5 ng/dl) by direct analog/radioimmunoassay. Calculated low density lipoprotein was reported using the Friedewald method. (9) Also collected were hormone therapy medication(s) used and dose(s), and the presence or absence of menses at 6 months (defined as self report of at least one full cycle time period without bleeding since last menses). Body mass index was calculated by usual method.

Results

A total of 57 (34 transgender men, 23 transgender women) patients were enrolled. All participants offered enrollment accepted. One eligible sequential participants was not enrolled due to an error with the registration process at the clinic not involving study staff. A total of 47 participants with a mean age of 28 (SD=8) completed the study and were included in the analysis (table 1). No patients had undergone gonadectomy at any time prior to or during the study. Baseline and 6-month median systolic and diastolic blood pressures and lipid measures were within a normal range for both transgender women and men (tables 2,3). (10,11,12) One female participant (6%) was HIV-positive. Dropout participants were more likely to be transgender women (7/10, $p=.035$); one of the three transgender male dropouts left the study only due to a change in insurance which led to them seeking care elsewhere The remainder of the dropouts occurred due to inability to adhere to study visit or lab draw schedules and practices.

Transgender women (persons assigned male at birth, but who identify as females and who use estrogens with or without an anti-androgen to develop female secondary sex characteristics) had normal median baseline and 6 month body mass index (24.8 kg/m² (IQR=4.3) and 23 kg/m² (IQR=4.5) respectively). Both systolic and diastolic median blood pressures in this group dropped significantly from baseline to 6 months (130.5 mmHg (IQR 11.5) to 120.5 mmHg (IQR 15.5) $p=.006$; 78 mmHg (IQR 21) to 67 mmHg (IQR 12), $p=.001$ respectively).

Three transgender women were excluded from lipid analysis due to failure to adhere to fasting protocol at 6 month lab draw. All three had baseline total cholesterol < 200 mg/dl and low density lipoprotein < 120 mg/dl, two had triglycerides < 200 mg/dl, and one had high density lipoprotein = 56 mg/dl. One of these subjects had triglycerides = 262 mg/dl and two had high density lipoprotein = 34 mg/dl.

Baseline estradiol levels for transgender women were within the male physiologic range in 14/15 (93%) (1 sample was not run due to hemolysis, this subject was excluded from baseline and pairwise estradiol analysis), however 4/16 (25%) had baseline total testosterone levels below the male physiologic range, 3 of whom also had free testosterone levels below the male physiologic range; an additional transgender woman with borderline low baseline total testosterone also had a low baseline free testosterone. All transgender women had

estradiol levels at least in the physiologic female – range at 6 months, with 3/16 (19%) having supraphysiologic levels > 1000pg/dl (including the one transgender woman using intramuscular estradiol valerate). At 6 months, free testosterone was in the female physiologic range in 14/15 (93%), however only 10/15 (66%) had total testosterone levels in the female physiologic range (Table 4). One transgender woman with elevated free and total testosterone levels at 6 months had chosen not to take spironolactone out of a desire to retain erectile function; data for this subject were excluded from testosterone analyses. Free and total testosterone levels in transgender women at 6 months were positively correlated with age ($\rho=0.68$, $P=0.004$).

Transgender men (persons assigned female at birth, but who identify as males and use testosterone to develop male secondary sex characteristics) had median baseline body mass index at the upper limit of the overweight threshold (29.1 kg/m^2 , IQR 11.2) and mean 6 month body mass index was in the obese range (30.0 kg/m^2 , IQR 11.4) ($p=0.024$). Statistically significant differences were also found in transgender men between baseline and 6 months for median weight (78.0 kg (IQR 45.4) to 79.4 kg (IQR 36.2), $p=0.024$) and median high density lipoprotein (58 mg/dl (IQR 22) to 56 mg/dl (IQR 29), $p=0.006$).

All transgender men had baseline estradiol and free testosterone levels within the female physiologic ranges, however 6/31 (19%) had total testosterone levels > 48ng/dl but less than 80ng/dl. Six month lab results found only 9/31 (29%) transgender men with physiologic male range estradiol levels, 21/31 (68%) with physiologic male range total and 18/31 (58%) free testosterone levels (Table 5). Baseline and 6 month total testosterone showed weak positive correlation ($\rho=0.39$, $p=0.03$). Total testosterone at 6 months showed moderate negative correlation with body mass index at 6 months ($\rho=-0.42$, $p=0.018$). Induction of amenorrhea by 6 months occurred in 26/31 (84%).

Three transgender men were excluded from analysis due to failure to adhere to fasting protocol at 6 month lab draw. All three had baseline total cholesterol $\leq 185 \text{ mg/dl}$, low density lipoprotein $\leq 102 \text{ mg/dl}$, triglycerides $\leq 82 \text{ mg/dl}$, and high density lipoprotein $\geq 55 \text{ mg/dl}$. Low density lipoprotein values in one transgender man were excluded due to baseline triglycerides = 579 mg/dl.

Discussion

This study found normal range median blood pressure and median lipid values before and after 6 months of cross sex hormone therapy in a mixed sample of transgender women and men. Lipid findings are consistent with an Austrian sample of similarly young transgender subjects. (2) Observed weight and body mass index changes were modest at most.

Transgender women were generally healthy. Baseline and 6 month median body mass indices in transgender women were within a normal range. Statistically significant increase in triglycerides at 6 months was not clinically significant. The reduction in both systolic and diastolic blood pressure seen in transgender women may be due to hormone effects, reduced anxiety about clinic visits, or reduced overall stress due to progress in their physical

transition. This finding differs from prior publications which suggest an increase in blood pressure with estrogen treatment. (17)

Transgender women generally had 6 month hormone levels in the targeted range. The significance of baseline total and free testosterone levels below normal male levels in 25% of transgender women is unknown. While 33% of transgender women had total testosterone levels elevated above the normal female range at 6 months, only 7% had an elevated free testosterone at 6 months. This may be due to a rise in sex hormone binding globulin seen in exogenous estradiol administration. Positive correlation of testosterone levels at 6 months with age suggests differences in drug metabolism or adherence patterns. All transgender women had physiologic estrogen levels at 6 months suggesting that the regimens used are appropriate, though 6 month estradiol levels were above female normals in 3/16 (19%) subjects. Given these findings it is reasonable to check estradiol and free and total testosterone levels at least once in transgender women after several months of treatment to optimize therapy.

Transgender men were less healthy from a metabolic standpoint. Elevated median baseline body mass index in transgender men is consistent with a prior Japanese study which found an increased prevalence of metabolic disorders and the polycystic ovarian syndrome (PCOS) in this population. (16) Baseline total testosterone levels between 45 and 80 ng/dl in 20% of transgender men is also suggestive of PCOS, however further data components of the PCOS diagnostic criteria (hirsutism, oligomenorrhea) were not collected in this study. A statistically significant decrease in median high density lipoprotein in transgender men was not clinically relevant.

Transgender men were also inconsistent in achieving target hormone levels. Persistent elevations of estradiol levels above normal male levels at 6 months in 71% of subjects is consistent with existing data. Such findings might help to inform the evaluation of transgender men on testosterone treatment who present with symptoms of bleeding, pelvic pain or other estrogenic features. (22) Only some 2/3 of transgender men achieved physiologic free (58%) and total (68%) testosterone levels, and 16% had persistent menses at 6 months. Moderate and weak negative correlations of body mass index with total and free testosterone respectively were seen at 6 months. These findings support the monitoring of testosterone levels to allow dosage titration, particularly in overweight transgender men and when using subcutaneous testosterone.

Recruitment faced numerous challenges including staff and scheduling factors and numerous competing priorities encountered in a community clinic setting. The study site serves a dense urban catchment area of 100 miles, complicating subject ability to adhere to study visit schedules or lab fasting requirements. The 82% completion rate for those enrolled is noteworthy in this setting and is a result of active retention activities which included text message and telephone reminders. That transgender women subjects were more likely to drop out suggests more intensive retention activities are needed for research involving transgender women. This consecutive sample shows a 2:1 transgender man to woman ratio, which differs from prior studies showing more balanced ratios, (13) or even skewing towards transgender women. (14,15) While enrollment failed to meet the target N

of 75 due to issues of scheduling and clinic capacity, only one eligible subject was missed during the enrollment period due to a scheduling error.

The study had several limitations. This sample was young and relatively healthy and was not representative of the diversity of the local population. Data were not collected on potential subjects who did not meet inclusion criteria. The skewed sample toward transgender men could be due to secular trends or due to exclusion of sequentially presenting transgender women who had been on previously self-directed hormone therapy. Medication adherence was not tracked. Dropout rate of 18% could mean that sicker or more psychosocially complex subjects were excluded from analysis. The study was underpowered, with limited data points collected due to funding limitations. Nevertheless findings suggest that transgender people receiving cross-sex hormone therapy do not develop abnormal blood pressure or lipids in the short term. Cross-sex hormone therapy was associated with a reduction in blood pressure in transgender women and there was an association with increased body mass index in transgender men. Needed research on transgender populations appears feasible in a community setting.

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Table 1

General sample demographics, race, and ethnicity.

	Transgender Female	Transgender Male
N (%)	16 (34%)	31 (66%)
Age (years)		
Mean	29	27
Minimum	19	18
Maximum	50	45
SD	9.4	6.9
Race		
White	11 (69%)	25 (80%)
Black	1 (6%)	3 (10%)
Asian	2 (12%)	2 (6%)
Native American/Hawaiian	1 (6%)	1 (3%)
Other	1 (6%)	0 (0%)
Latino (any race)	6 (38%)	11 (35%)

Table 2

Baseline and 6 month biometrics for transgender women (N=16). All statistical analysis using the wilcoxon signed-rank test for paired samples. IQR = interquartile range. NS = nonsignificant.

	Baseline median (IQR)	6 month median (IQR)	p
Height (cm)	172.5 (12)	---	---
Weight (kg)	69.4 (17.9)	68.8 (20.2)	NS
Body Mass Index (kg/m²)	24.8 (4.3)	23 (4.5)	NS
Systolic BP (mmHg)	130.5 (11.5)	120.5 (15.5)	0.006
Diastolic BP (mmHg)	78 (21)	67 (12)	0.001
Total Cholesterol (mg/dl)	171 (50)	176.5 (42)	NS
High density lipoprotein (mg/dl)	58.5 (16)	66.5 (25.5)	0.049
Low Density Lipoprotein (mg/dl)	97 (42)	89.5 (20.5)	NS
Triglycerides (mg/dl)	71.5 (37.5)	94 (65.5)	0.013

Table 3

Baseline and 6 month biometrics for transgender men (N=31). All statistical analysis using the wilcoxon signed-rank test for paired samples. IQR = interquartile range. NS = nonsignificant.

	Baseline median (IQR)	6 month median (IQR)	p
Height (cm)	164 (9)	---	---
Weight (kg)	78 (45.4)	79.4 (36.2)	0.024
BMI (kg/m²)	29.1 (11.2)	30.0 (11.4)	0.024
Systolic BP (mmHg)	120 (23)	123 (14)	NS
Diastolic BP (mmHg)	72 (16)	70 (16)	NS
Total Cholesterol (mg/dl)	177 (38)	178 (42)	NS
High density lipoprotein (mg/dl)	58 (22)	56 (29)	0.006
Low Density Lipoprotein (mg/dl)	93 (33)	97 (38)	NS
Triglycerides (mg/dl)	75 (56)	73 (69)	NS

Table 4

Hormone data for transgender women (N=16). IQR = interquartile range.

	Baseline median (IQR)	6 month median (IQR)	N with physiologic levels at 6 months
Estradiol (pg/dl)	29 (16)	258 (812)	16/16 (100%)
Total Testosterone (ng/dl)	405 (265)	42 (98)	10/15 (67%)
Free testosterone (ng/dl)	11.4 (6.7)	0.8 (1.7)	14/15 (93%)

Table 5

Hormone data for transgender men (N=31). IQR = interquartile range.

	Baseline median (IQR)	6 month median (IQR)	N with physiologic levels at 6 months
Estradiol (pg/dl)	61 (78)	53 (36)	9/31 (29%)
Total Testosterone (ng/dl)	37 (15)	545 (344)	22/31 (71%)
Free testosterone (ng/dl)	0.7 (0.6)	11(12.1)	20/31 (65%)