



Endocrine Therapy of Adult Gender-Incongruent Individuals Seeking Gender Reaffirmation

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Abstract

Gender-affirming hormone therapy (GAHT) is integral to the management of gender-incongruent (GI) individuals. GAHT greatly improves the quality of life for GI individuals. Current research about outcomes of GAHT and adverse events in adults receiving GAHT is limited in India and large cohort studies are absent. This document on medical management provides protocols for the prescribing clinician relating to counseling for GAHT, baseline evaluation, choice of therapy, targets for hormone therapy, clinical and biochemical monitoring, and perioperative hormone therapy.

Keywords

- ▶ gender-affirming hormone therapy
- ▶ gender incongruent
- ▶ transfeminine
- ▶ transmasculine
- ▶ transgender
- ▶ hormone therapy

Introduction

Gender-affirming hormone therapy (GAHT) is a necessary medical intervention for gender-incongruent (GI) individuals seeking gender reaffirmation. However, not all GI individuals seek GAHT. Moreover, social taboo, lack of information, and poor family support lead to delayed medical consultation and account for complexities in the therapy.¹ An effective GAHT regimen suppresses endogenous sex-specific hormone secretion and maintains physiological levels of sex hormone that is consistent with the desired sex. The changes in secondary sexual characteristics facilitate gender presentation of the desired sex. Hormone therapy is associated with a lot of benefits but many risks are present as well, and unsupervised use of hormones is strongly discouraged.² The situation is often further complicated in India with prior breast surgery and/or prior bottom surgery in both transfeminine and transmasculine individuals without following an acceptable protocol-wise approach.^{1,3,4} Educating the GI individuals undergoing GAHT about the onset and time

course of physical changes induced by hormone treatment and the benefits and risks associated with hormone treatment is essential for a successful outcome. Nonspecialists might also be approached for help by GI individuals and can play an important role in counseling and referring them to a gender clinic.⁵ Nonspecialists might also consider prescribing hormonal treatments while the patient is awaiting specialist consultation.⁵ Tailoring the currently available protocols may be done within the context of accepted safety guidelines.² The practical suggestions on the assessment and management in this article are largely based on the experience of the author and the few existing national⁶ and international² guidelines.

Assessment of the Gender-Incongruent Individuals Seeking Gender Reaffirmation

People in a new gender role usually need lifelong support of maintenance hormone therapy, and specialist clinicians

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involved in the care of GI individuals should assess and evaluate the subjects before starting the GAHT.

Counseling

Following issues need to be discussed before starting hormone therapy:⁶

1. Potential effects along with potential risks, limitations, and adverse effects of the hormone therapy.
2. Prospects of gamete conservation, even though associated with potential cost implications.
3. Adoption of a healthy lifestyle with regard to body weight and substance abuse.
4. Confirmation that the patient can understand the consequences and is capable of taking hormones in a responsible manner.
5. That hormonal therapy is usually continued indefinitely, even following gender-affirming surgeries.

Baseline Evaluation⁶

Physical: Height, weight, body mass index, blood pressure, and examination of breasts and genitalia and digital rectal examination for prostate.

Laboratory investigation: Hemoglobin or hematocrit, glycosylated hemoglobin, potassium, urea, creatinine, lipid profile, thyroid function tests, liver function tests, prolactin, testosterone, estradiol, hepatitis B surface antigen, anti-hepatitis C antibody, venereal disease research laboratory test, and tests for human immunodeficiency virus. Karyotype testing is optional as is the evaluation of prostate-specific antigen.⁶

Endocrine Therapy of GI Individuals-Seeking Gender Reaffirmation as Female (Transfeminine)

Estrogens and antiandrogens are commonly used in clinical practice, which effectively suppresses endogenous testosterone level and promotes feminization in transfeminine individuals. However, there is no randomized controlled trial data available to determine which route and preparation of estradiol and the type of antiandrogen are most effective.⁷

Estrogen Therapy

Estrogen is the cornerstone for feminization and estradiol level is to be maintained in the normal physiological range for cis-female. However, there are not lots of data on how best to achieve this. Typically, it requires suprphysiological doses (– **Table 1**). Estrogen is not enough to suppress endogenous testosterone production and there is a need for concomitant antiandrogen or gonadotropin-releasing hormone (GnRH) analog therapy in most individuals. The estrogen dose requirement is more in those who are not receiving GnRH therapy and in those with preserved testes.⁶ Estrogen therapy should be started at lower doses and titrated upward over the course of a year, similar to the induction of puberty in natal girls in whom rapid estrogen exposure leads to poor breast development.⁸

Table 1 Estrogen regimens for transfeminine individuals²

Preparations	Dose
Oral estradiol (valerate)	2.0–6.0 mg/day
Transdermal estradiol patch	25–200 µg/day (new patch every 3–5 days)
Parenteral estradiol valerate	5–30 mg IM every 2 weeks 2–10 mg IM every week

Abbreviation: IM, intramuscular.

Breast growth, increased body fat, slowed growth of body and facial hair, decreased testicular size, and erectile function are the expected benefits of estrogen therapy. The time interval for the maximum benefits to occur varies across the transfeminine population and may take up to 18 to 24 months. Antiandrogenic therapy helps to achieve maximum change.⁹

Despite a lot of variability in the response to various doses of estradiol, there is a positive correlation between increasing doses and serum levels of estradiol and a negative correlation with serum testosterone.⁸ However, a significant number of transfeminine individuals do not achieve the desired testosterone suppression despite reaching estradiol targets.⁸

Adverse Effects of Estrogen Therapy

1. Venous thromboembolism (VTE): Estrogens have increased risk of VTE. Increasing age and obesity are two important risk factors for VTE with estrogen use. Synthetic estrogen (ethinyl estradiol) and conjugated estrogens should be avoided because of the inability to regulate doses by measuring serum levels and possible increased risk of VTE.^{2,10} Despite insufficient data to inform associations between VTE and the dose, route, or duration of therapy, the strategy of changing to transdermal preparations are universally recommended based on data from observational studies of postmenopausal cis-gender women.¹⁰ However, transdermal preparation is expensive, not readily available, and is not much successful in tropical climate.⁶ Cessation of tobacco use should strongly be encouraged to avoid increased risk of VTE and cardiovascular complications.⁷
2. Hyperprolactinemia: A rise in prolactin level with the potential for development of a prolactinoma is a concern but mostly with estrogen–cyproterone regimens and not with estrogen–spironolactone regimen.^{2,10}
3. Breast cancer.²
4. Coronary artery disease.²
5. Cerebrovascular disease.²
6. Cholelithiasis.²
7. Hypertriglyceridemia.²

Contraindications of Estrogen Therapy⁶

1. Previous history of VTE
2. History of estrogen-sensitive neoplasm

Table 2 Progesterone regimens for transfeminine individuals

Preparations	Dose
Oral micronized progesterone ¹¹	200–300 mg/day
Oral MPA ¹³	5–20 mg daily
Parenteral MPA ⁹	150 mg IM every 3 months

Abbreviations: MPA, medroxy progesterone acetate; IM, intramuscular.

- Advanced stages of chronic liver disease
- Hypertriglyceridemia (relative contraindication)

Progestin Therapy

The use of progestins for transfeminine individuals is controversial⁷ and Endocrine Society Guideline recommends only estradiol as gender reaffirmation therapy.² However, evidence suggests that progesterone helps in feminization process, optimization of breast maturation, and increase in bone formation, and has possible cardiovascular health benefits.¹¹

Adverse effects of progestin therapy: Increased potassium level, depression, weight gain, lipid changes, increase in breast cancer risk, and possible suppression of the pituitary adrenal axis.¹²

Progestin preparations: Oral micronized progesterone is preferred and likely to be more beneficial for transfeminine individuals (→ **Table 2**). Desired effects are unique to micronized progesterone and not present in synthetic progestins, which also have adverse effects distinct from micronized form of progesterone.¹¹ Though low-priced, medroxyprogesterone acetate has been associated with an elevated risk of cardiovascular disease and breast cancer.¹⁰

Androgen-Reducing Therapy

Suppression of testosterone production and/or blocking its effects contributes to minimizing male secondary sexual characters and allows the use of lower estradiol dosing. However, there are no unanimous recommendations for the use of any specific antiandrogens, and many options are available (→ **Table 3**). Androgen-reducing medications are

Table 3 Antiandrogen regimens for transfeminine individuals

Preparation	Dose	Side effects and limitations
Spironolactone ⁷	100–300 mg daily	Hypotension, hyperkalemia
Finasteride ⁶	5 mg daily	Liver toxicity, erectile dysfunction (not an issue in transfeminine individual)
Cyproterone acetate ¹⁰	25–50 mg daily	Hyperprolactinemia and meningioma; not available in India
GnRH agonists ⁷	1. Triptorelin depot 3.75 mg monthly or 11.25 mg every 3 months (IM/SC) 2. Leuprolide 3.75 mg monthly or 11.25 mg every 3 months (IM/SC) 3. Goserelin 3.6 mg monthly or 10.8 mg every 3 months (SC)	Decrease libido, decrease bone mineral density, expensive, and need to be injected

Abbreviations: GnRH, gonadotropin-releasing hormone; IM/SC, intramuscular/subcutaneous; SC, subcutaneous.

the first-line therapy, as it reduces endogenous testosterone levels or activity. GnRH analogs are preferred the first line of therapy but spironolactone with/without finasteride is a reasonable alternative in a resource-limited settings.³ Spironolactone facilitates breast augmentation and benefits facial hair growth but lacks an independent effect on androgen level.⁸ Many transgender women seek breast augmentation due to dissatisfaction in hormonal therapy and spironolactone use is more common in those seeking augmentation. Spironolactone may have a negative impact on breast development in the presence of estrogen when it behaves as a competitive inhibitor.⁸ Avoidance of spironolactone may maximize the breast growth but no study has confirmed this approach.

Adverse effects of androgen-reducing therapy: GnRH analogs as antiandrogens, as proposed by the Endocrine Society Guidelines,² are well tolerated with satisfactory results. Cheaper alternatives (spironolactone and finasteride) may have some undesirable effects.

Ancillary Therapy (Eflornithine and Laser)

Decrease in male-pattern hair growth may not be sufficiently achieved by hormone therapy alone and to achieve further cutaneous change, eflornithine and laser are often used as ancillary therapies.¹⁴

Eflornithine is an inhibitor of ornithine decarboxylase and reduces unwanted facial hair when applied twice daily in the area of skin under the chin. Improvement may be observed only after 8 weeks and needs to be continued for an indefinite period. On the other hand, laser reduces hair growth permanently and can be applied in a larger area.¹⁴

Targets for Hormone Therapy

The biochemical targets for testosterone and estradiol in a transfeminine individual undergoing hormone therapy were laid down by the Endocrine Society² (→ **Table 4**) and adopted in the Indian consensus statement as well.⁶

Monitoring

All GI individuals seeking gender reaffirmation as female with cross sex hormone therapy should check hormone levels to monitor adequacy of therapy, to avoid

Table 4 Hormonal targets for transfeminine individuals

Serum testosterone	Less than 50 ng/dL
Serum estradiol	100–200 pg/mL

overtreatment (supraphysiologic levels >200 pg/mL), and to evaluate any upcoming adverse effects (► **Table 5**). The effects of estrogen on cardiovascular disease in transfeminine individuals are not very conclusive, but show a trend toward an increased risk of heart disease. Presence of diabetes, tobacco abuse, and the use of oral ethinyl estradiol appear to be strongly associated with cardiovascular events.⁹

Hormone therapy during and after sex reaffirmation surgery:⁶

1. Estrogen should be stopped 4 weeks before surgery to reduce risk of VTE and patient may receive a single dose of GnRH for the interim period.
2. GnRH and spironolactone may be stopped after orchiectomy.
3. Reevaluate the need of hormones after surgery, and estrogen may be resumed 4 weeks postoperatively if there are no complications.
4. Estrogen dose may be reduced after breast augmentation surgery.
5. Only transdermal estrogen should be used if VTE is encountered during perioperative period.

Endocrine Therapy of GI Individuals Seeking Gender Reaffirmation as Male (Transmasculine)

Testosterone is used to induce virilization and appears safe.¹² Different testosterone formulations are available in different parts of the globe. The most commonly prescribed regimens are discussed below (► **Table 6**).

Cessation of menses, increased facial and body hair, increased acne, changes in fat distribution, increase in muscle mass, and increase in libido occur within few months of initiation of androgen therapy. Deepening of the voice, atrophy of the vaginal epithelium, increased clitoral size, and male-pattern hair loss also occur over time with the continuation of the therapy. However, shorter stature and broader hips than biologic males and some degree of feminine subcutaneous fat distribution cannot be reversed with exogenous androgen therapy in most transmasculine individuals (unless testosterone is administered during the peripubertal period).^{9,10}

Table 5 Monitoring protocol for transfeminine individuals

Year	Frequency	Parameter to test
First year	Every 3 months	Weight, blood pressure, hematocrit, creatinine, testosterone, estradiol, potassium (if receiving spironolactone), prolactin, glucose, lipid profile, LFT, thyroid function test, DXA (at age 60 years and above)
Second year onward	One to two times per year	

Abbreviations: DXA: dual-energy X-ray absorptiometry; LFT, liver function test.

Table 6 Androgen regimens for transmasculine individuals

Preparations	Dose
Testosterone gel (1.6%) ²	50–100 mg per day
Testosterone depot (enanthate or cypionate) ²	100–200 mg IM every 2 weeks
Testosterone undecanoate ²	1,000 mg every 12 weeks

Abbreviation: IM, intramuscular.

No differences were found regarding short-term safety, compliance, body composition, metabolic parameters, and general life satisfaction in three different testosterone formulations (testoviron depot 100 mg, testosterone gel 50 mg/die, and testosterone undecanoate 1,000 mg) evaluated in one study.¹⁵ However, target testosterone levels are more easily achieved with parenteral therapy but more uniformly with transdermal therapy.¹⁰ Androgen therapy may be continued lifelong to maintain the achieved virilization and appears safe even in elderly transmasculine individuals. Cessation of the therapy leads to hypogonadism with vasomotor symptoms and osteoporosis.¹²

Adverse Effects of Testosterone Therapy

Sustained intentional use of supraphysiologic dose of testosterone may produce following adverse reactions.²

1. Testosterone undecanoate is associated with the potential risk of oil pulmonary embolus.¹²
2. Worsening of cardiovascular risk factors (increase in hematocrit, decrease in high-density lipoprotein cholesterol, increase in triglycerides, increase in low-density lipoprotein cholesterol levels, increase in systolic blood pressure, and a decrease in adiponectin and leptin) is commonly observed.¹² Despite perceived negative impact of these risk factors, testosterone treatment does not result in adverse cardiovascular outcomes.¹²
3. Severe liver dysfunction (transaminases more than three-fold upper limit of normal).²
4. Sleep apnea.¹⁰
5. Breast or uterine cancer:² Most guidelines raised the concern of increased risk of breast or endometrial cancer in association with androgen therapy in transmasculine patients, and hysterectomy may be considered to avoid the risk of endometrial cancer.¹⁰

Therapy to Stop Menstrual Bleeding

If menstrual bleeding does not stop after initiation of testosterone (mostly with the use of transdermal or oral

Table 7 Agents to stop menstrual bleeding for transmasculine individuals

Preparations	Dose
Oral lynestrenol ¹²	5–10 mg daily
Oral medroxyprogesterone ¹²	5–10 mg daily
Depot medroxyprogesterone ²	150 mg deep IM every 3 months
GnRH analogs ²	1. Triptorelin depot 3.75 mg monthly or 11.25 mg every 3 months (IM/SC) 2. Leuprolide 3.75 mg monthly or 11.25 mg every 3 months (IM/SC) 3. Goserelin 3.6 mg monthly or 10.8 mg every 3 months (SC)

Abbreviations: GnRH, gonadotropin-releasing hormone; IM, intramuscular; IM/SC, intramuscular/subcutaneous; SC, subcutaneous.

testosterone), a progestational agent or GnRH analog is used to stop the menstruation (►Table 7).¹²

Transmasculine individuals mostly prefer testosterone or testosterone plus medroxyprogesterone. GnRH analogs are effective but rarely used given the costs of the therapy.⁴ The progestational medication can be discontinued after ovariectomy.¹²

Targets for Hormone Therapy

Transgender-specific hormone data for the monitoring purpose are lacking and the strategies used for cis-gender persons are usually recommended to be followed.¹⁰ The biochemical targets for testosterone and estradiol in a transmasculine individual undergoing hormone therapy are laid down by the Endocrine Society (►Table 8).²

Monitoring

Testosterone level should carefully be monitored to avoid a prolonged hypogonadal state, if dosing is too low with a possibility of loss in bone mineral density, and to avoid exposures to high level, with a possibility of significant physiological and metabolic effects. Both testosterone and estradiol are necessary for bone health in men and women, respectively. Exogenous testosterone appears to have an anabolic effect on bone and is capable in preventing bone loss with adequate dose in transmasculine individuals. Hypogonadal states can result in clinically significant bone

loss and need to be monitored (►Table 9). It is not clear whether use of exogenous testosterone increases the risk of cardiovascular disease in transmasculine individuals or not. The role of testosterone in increasing the risk of cardiovascular events is debatable but testosterone significantly alters many cardiovascular risk markers (blood pressure, total cholesterol, high-density lipoprotein cholesterol, triglycerides, and inflammatory markers).⁹

Cancer Screening

There are limited data on cancer outcomes for GI individuals as there are no large long-term prospective studies investigating cancer incidence and mortality in GI population. The currently available evidences do not show that GAHT increases the risk of cancer in GI individuals and hence, the very few existing transgender-specific cancer screening recommendations are mostly extrapolated based on evidence in the cis-gender population.¹⁶ GI individuals who have undergone sex reaffirmation surgery may have a possibility of cancer from the residual reproductive tissue that may have been left behind after surgery.

A comprehensive cancer screening and prevention initiative is based on the best practices cancer screening protocol published recently.¹⁶ In transfeminine patients, we conventionally follow cis-female guidelines for breast cancer screening, cis-male guidelines for prostate cancer screening, and annual anal pap smear who have multiple lifetime sexual

Table 8 Hormonal targets for transmasculine individuals

Preparation	Measurement	Targets
Testosterone enanthate/cypionate injections	Measured midway between injections	400–700 ng/dL
Testosterone undecanoate	Measured just before the following injection	400–700 ng/dL
Transdermal testosterone	Measured after 1 week of daily application (at least 2 hours after application)	400–700 ng/dL

Table 9 Monitoring protocol for transmasculine individuals^{2,9}

Year	Frequency	Parameter to test
First year	Every 3 months	Weight, blood pressure, testosterone, estradiol (during the first 6 months and thereafter until uterine bleeding has ceased), hematocrit or hemoglobin, lipids, and DXA (who stop or are irregular in testosterone treatment)
Second year onward	One to two times per year	

Abbreviation: DXA: dual-energy X-ray absorptiometry.

Table 10 HPV vaccination recommendation¹⁸

Age	Recommendation
Children and adults aged 9–26 years	HPV vaccination is routinely recommended at age 11 or 12 years and can be given starting at age 9 years; catch-up HPV vaccination is recommended for all persons through age 26 years who are not adequately vaccinated
Adults aged 26–45 years	Catch-up HPV vaccination is not recommended for all adults aged >26 years; instead, shared clinical decision-making regarding HPV vaccination is recommended for some adults aged 27–45 years who are not adequately vaccinated
Adults aged >45 years	HPV vaccines are not recommended

Abbreviation: HPV: human papillomavirus.

partners. In transmasculine patients, we follow cis-female guidelines for breast cancer screening prior to bilateral mastectomy and cervical cancer screening prior to hysterectomy. Currently, there is no recommendation for breast cancer screening after bilateral mastectomy in this population.

Human Papillomavirus (HPV) Vaccination

There is a high rate of human papillomavirus (HPV) infection among transfeminine individuals and among the men who have sex with men.¹⁷ Vaccines against HPV were first introduced in 2006. Quadrivalent and 9-valent HPV vaccines (Gardasil and Gardasil 9) protect against anal, cervical, oropharyngeal, penile, vaginal, and vulvar cancers caused by HPV.¹⁸ HPV vaccination ought to be suggested to all age-eligible adolescents and young adults regardless of behavioral or medical risk factors for HPV infection or disease. Although vaccination ideally occurs prior to HPV exposure (before onset of sexual activity), recommendations support vaccination of the vulnerable individuals who are within the recommended target age range for vaccination, even if they are already sexually active¹⁷ (► **Table 10**). Additional proof is required to develop national recommendations regarding appropriate screening and vaccination for HPV-related diseases among GI individuals in India. Shared clinical decision-making for adults aged 26 to 45 years ought to be based on following three information:¹⁸

1. A long-term, mutually monogamous sexual partnership is not likely to acquire a new HPV infection and no vaccination is needed.
2. Vaccine effectiveness might be low among persons with multiple lifetime sex partners and likely previous infection with vaccine-type HPV and vaccination will not be helpful.
3. At any age, having a new sex partner is a risk for acquiring HPV infection and vaccination may be helpful.

Conclusion

GAHT consistently improves quality of life and mental health and has modest effects on secondary sexual development. Adult GI individuals seeking GAHT require a safe and effective hormone regimen. Although hormone therapy is integral to the management, there is no uniformity in the dose, formulation, and mode of therapy in different gender clinics.

Initiation of GAHT, monitoring the ongoing care, regular evaluation for adverse drug reactions, and monitoring for known cancer risks are the key factors for a successful hormone therapy.

Conflicts of Interest

None.

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