#### **REVIEW**



# Pregnancy in Transmasculine, Non-binary, and Gender Expansive Patients

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#### **Abstract**

**Purpose of Review** Transgender, non-binary, and gender expansive (TNGE) patients may choose to become pregnant and will require pregnancy-related care. To date, there has been limited research on pregnancy in this community. This review article aims to collate and summarize the most recent literature and make recommendations for providing pregnancy care to TNGE patients.

**Recent Findings** TNGE patients can successfully undergo fertility preservation before or after starting their gender transition and may be able to continue gender-affirming hormone therapy with testosterone (GAHT-T) during the process. GAHT-T is potentially teratogenic and should be discontinued in pregnancy; however, GAHT-T does not appear to affect birth outcomes in TNGE patients. Clinicians should be aware that pregnancy can have profound physical and psychosocial impacts on TNGE patients, and patients frequently identify a lack of knowledgeable providers and welcoming care settings as barriers to care. Postpartum TNGE patients may be at increased risk of postpartum mood disorders. They may also choose to chest feed and require extra support and accommodations to be successful in this endeavor.

**Summary** TNGE patients should be provided the same standard pregnancy-related care as their cisgender counterparts. Special consideration should be given to fertility preservation, contraception, postpartum mood disorders, and lactation/chest feeding as TNGE patients have unique needs within these areas. Much of the available research in this population is retrospective and qualitative with small sample sizes. Future research should focus on larger-scale quantitative studies to help develop evidenced-based, community-informed guidelines for care.

**Keywords** Pregnancy · Fertility · Fecundity · Transmasculine · Non-binary · Gender expansive

# Introduction

Between 2012 and 2022, the percentage of the U.S. LGBT population has continually increased [1]. As of 2022, 0.6% of the population identified as transgender; that percentage increases to 1.0% specifically among Millennials and is more than triple the general population percentage at 1.9% with Generation Z [1]. Like with any other burgeoning community within a population, the transgender community will experience increasing visibility and exposure to all aspects of society, including medical care. The preliminary report from the 2022 U.S. Transgender Survey, the largest survey of the transgender lived experience to date with over 92,000

respondents, states that nearly one quarter (24%) of respondents did not see a clinician in the last 12 months when they needed to due to fear of mistreatment, and of those that did, nearly half (48%) reported having at least one negative experience directly related to their transgender identity [2]. Both perceived and actual fear may prevent an ever-increasing proportion of the population from accessing needed care.

To better care for this unique community, clinicians must strive to understand the unique and varied lived experiences of its members. That starts with understanding how this community is defined. The word transgender is an umbrella term often used to represent "gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth" [3••]. Gender is a social and cultural construct that is contextually dependent and refers to the identity, outward physical expression, and role that one is expected to display in a given society based on the sex assigned at birth (designation of male, female, or intersex typically made based on the physical and anatomic

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appearance of the external genitalia and/or genetic sex chromosome makeup) [3••]. In many Western cultures, gender exists as a binary between man/masculine and woman/feminine. Recent sociological research suggests that gender may instead be better represented on a continuum with the traditional binaries situated at either end [4]. On one portion of this continuum are people who identify as transmasculine, non-binary, or gender expansive. Assigned female at birth (AFAB) individuals can fall along this continuum if any part of their gender identity aligns with the traditional male/masculine role. Table 1 highlights additional terminology and definitions that will be used throughout this review article.

Historically, it was assumed that transmasculine individuals did not desire pregnancy, and in some places, governments have gone so far as to require sterilization in order for people to access gender-affirming care [5]. However, studies have shown that transmasculine individuals often do desire and can successfully achieve pregnancy, both before and after starting their gender transition journeys [6, 7]. Although significant strides have been made in recent years to better understand pregnancy in transmasculine people, there remains a dearth of research regarding pregnancy in AFAB individuals who identify somewhere along the masculine portion of the continuum. The purpose of this

review article is to summarize and evaluate the most recent literature regarding pregnancy in this patient population. This author recognizes that the concept of gender identity in society is rapidly changing and expanding. This article will use the terms transmasculine, non-binary, and gender expansive (TNGE) to refer to AFAB individuals who are capable of pregnancy and identify anywhere along the masculine portion of the gender spectrum with the understanding that there are infinite ways that one can choose to identify and that these terms may not reflect all people who can become pregnant.

# **Creating an Inclusive Health Care Environment**

TGNE patients face barriers to accessing health care including lack of knowledgeable, well-trained clinicians, discrimination in health care settings, and outright refusal of care [8–11]. Many narrative studies exploring TNGE patient experiences accessing care also provide insight into ways that healthcare providers can make their care practices more welcoming. Suggested changes included using gender-neutral language on intake forms and office signage, asking for and using desired pronouns, documenting the patient's gender identity

Table 1 Common terms and definitions

Term	Definition <sup>a</sup>
Sex	A medical label applied at birth typically based on the appearance of the external genitalia but that can also be assigned based on the presence or absence of the Y chromosome. In Western cultures, the binary terms typically used for sex are male and female with those not falling into one of the two binary categories being labeled intersex.
Sexual orientation	A person's innate sense of who they are physically, romantically, or sexually attracted to. This can only be determined by the individual, can be fluid, and can exist on a continuum. This is separate and distinct from one's gender identity.
Gender	A social construct that is used to categorize individuals within a society and inform the individual's role in society in relation to power structures, physical appearance, and other culturally specific categories. In Western cultures, the binary terms typically used for gender are men and women. Historically, this has been imposed on an individual based on their sex assigned at birth
Gender identity	A person's innate sense of their true gender irrespective of the gender that was imposed on them at birth. This can only be determined by the individual, can be fluid, and often exists on a continuum. This is separate and distinct from one's sexual orientation
Gender expression	How one presents their gender in society. This can include choices in mannerisms, speech, and clothing and can vary in different social settings.
Cisgender	When one's gender identity is congruent with the gender associated with their sex assigned at birth within a specific cultural context.
Transgender	When one's gender identity is incongruent with the gender associated with their sex assigned at birth within a specific cultural context.
Non-binary	When one's gender identity does not align with the traditional Western gender binary of man or woman. Individuals may identify as both a man/woman simultaneously, as either more a man or more a woman intermittently, or as neither a man nor a woman.
Gender expansive	When one's gender identity does not lie within the current confines of a society's concept of gender and seeks to expand the concept beyond the current definition within a specific cultural context.
Gender dysphoria	A medical diagnosis for the mental distress and/or physical discomfort experienced by an individual when their gender identity does not align with how their gender is perceived by the society in which they live.

<sup>&</sup>lt;sup>a</sup>Definitions are based on the author's own clinical knowledge and are informed by a Western cultural lived experience. Other cultures, traditions, and lived experiences may lead to variations in some of the above definitions



correctly in the medical record, ensuring that support staff are trained on gender-inclusive language, and not expecting TNGE patients to educate their providers [9, 12–16].

# **Prepregnancy Care**

# **Routine Prepregnancy Care**

No discussion of pregnancy care would be complete without first discussing appropriate prepregnancy care. This is also true regarding pregnancy in TNGE patients. The American College of Obstetricians and Gynecologists (ACOG) makes specific recommendations for prepregnancy care in their "Committee Opinion No. 762." These include general counseling on wellness and healthy habits, assessment of patient goals for timing of pregnancy, optimization of comorbid conditions that can affect pregnancy, reviewing options for genetic screening, ensuring the patient is up to date on routine vaccinations, assessing immunity status, and reviewing prescriptions and over-the-counter medications currently being taken by the patient [17]. This author endorses the ACOG committee opinion and recommends applying these same standards of care to TNGE patients who seek prepregnancy counseling.

#### **Fertility Preservation**

While many aspects of prepregnancy care for TNGE patients are the same as for their cisgender counterparts, there are some special considerations that should be noted. The first is regarding fertility preservation. Many TNGE patients will choose to pursue gender-affirming care to help better align their physical appearance and internal/external anatomy with their gender identity. For TNGE patients, this can include masculinizing hormone therapy with exogenous testosterone and/or masculinizing surgery. The World Professional Association for Transgender Health (WPATH) in their "Standards of Care for the Health of Transgender and Gender Diverse People, Version 8" and ACOG in their "Committee Opinion, No. 862 Health Care for Transgender and Gender Diverse Individuals" recommend that all patients seeking gender-affirming hormonal or surgical care be adequately counseled on the effects that this care may have on their fertility and on options for preserving that fertility prior to initiating care [3••, 18]. Many TNGE patients may have already initiated gender-affirming hormone therapy when they present for a prepregnancy counseling visit. In one study, more than 75% of transgender patients surveyed reported thinking about preserving their own germ cells, but only 3.1% had actually taken steps to do so [7].

While the effects of gender-affirming surgeries such as hysterectomy and bilateral oophorectomy on future fertility are more concrete, the data are less clear on the effects of gender-affirming hormone therapy with testosterone (GAHT-T) [19]. A systematic review by Baram and colleagues found that there were significant barriers that prevented transgender adolescents and young adults from pursuing fertility preservation services, including lack of awareness of options, high cost, and the invasiveness and psychological effects of fertility preservation procedures/processes [20]. Armuand et al. reported similar concerns regarding fertility preservation in adult TNGE patients [21]. They highlighted clinician-led steps to reduce dysphoria and community-driven approaches for coping such as focusing on their own personal reasons for pursuing fertility preservation, relying on friends and family for support, and using non-gendered language for certain anatomy [21].

For TNGE AFAB individuals who desire fertility preservation of their own gametes, the primary option is ovarian stimulation and oocyte retrieval with either oocyte cryopreservation or subsequent fertilization and embryo cryopreservation [20]. Ovarian tissue cryopreservation is still considered experimental, and at least one study has shown a low developmental capacity for oocytes matured in vitro from ovarian tissue obtained after gender-affirming surgery in transgender men currently receiving GAHT-T [20, 22]. Additional studies will be needed to determine if this effect is permanent or reversible before ovarian tissue cryopreservation can be considered for fertility preservation in TNGE patients on GAHT-T. There does not appear to be a decrease in functional ovarian reserve in TNGE patients on GAHT-T [23]. TNGE patients can have successful ovarian stimulation and oocyte retrieval even after long-term testosterone use [24–27]. Currently, there are no set guidelines on the necessity or duration of testosterone therapy cessation prior to ovarian stimulation and oocyte retrieval. In a recent retrospective cohort study, Albar and colleagues found no association between the timing of testosterone cessation and the number of mature oocytes retrieved [28]. To date, there are at least two reported cases of patients who were maintained on testosterone therapy during ovarian stimulation and oocyte retrieval as a proof of concept [29...]. One of these retrieved oocytes was successfully fertilized with donor sperm and transferred into the oocyte donor's partner resulting in an uncomplicated pregnancy with subsequent live birth [29••]. There currently are no long-term data on the health of children born from testosterone-exposed oocytes [29••].

Current research has shown that fertility preservation via ovarian stimulation, oocyte retrieval, and oocyte vs. embryo cryopreservation is a feasible option for TNGE patients [21–28, 29••]. Further research is needed to determine the optimal protocols for ovarian stimulation and oocyte retrieval for TNGE patients on GAHT-T. For now, the decision to stop testosterone and for how long prior to fertility preservation procedures should be made using a shared decision-making model between the patient and the reproductive endocrinology team caring for the patient.



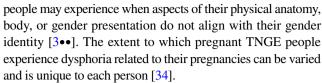
# Effects of Gender-Affirming Hormone Therapy with Testosterone on Fertility and Pregnancy

Regardless of whether fertility preservation is undertaken, some TNGE patients may desire pregnancy. For many, this may occur after having initiated GAHT-T. It is imperative that clinicians be able to counsel these patients on the effects of testosterone on their fertility and fecundity. Currently, there is insufficient research on the incidence of pregnancy in TNGE patients receiving regular testosterone injections with appropriate cis male physiologic testosterone levels [30]. Schubert and Carey raise the concern that overstating the risk of pregnancy for TNGE patients on or desiring GAHT with testosterone may lead to decreased access due to prescribing providers refusing to write for testosterone unless the TNGE patient is on effective contraception. Injectable testosterone likely leads to rapid suppression of the hypothalamic-pituitary-ovarian axis in new users resulting in anovulation [31], and timing for when ovulation will occur again after discontinuing testosterone if pregnancy is desired is not known. One study reported that 80% of transgender men who were on GAHT-T before becoming pregnant had resumption of menses (a clinical indicator of ovulation) within 6 months of stopping testosterone [6]. However, even patients on long-term injectable testosterone may have breakthrough ovulatory events [31]. As such, testosterone should not be considered an effective form of contraception. Unfortunately, some TNGE patients may believe that testosterone is an effective contraception given that there is often menstrual cessation with its use, and some may have actually been advised of this by an uneducated clinician [32].

Because of these misconceptions among both patients and providers and the possibility of ovulatory events while on long-term testosterone therapy, TNGE AFAB patients with intact anatomy who engage in receptive vaginal intercourse with partners who can produce sperm should use alternative contraception to prevent an unintended pregnancy. TNGE patients who desire pregnancy or who present with a positive pregnancy test should be counseled that complete cessation of testosterone is recommended due to the potential teratogenic effects on female fetuses [33].

#### Physical and Psychosocial Effects of Pregnancy

Pregnancy causes various anatomic and physiologic changes in the body. These can include, but are not limited to, increasing the size of mammary tissue, redistribution of body fat, and an enlarged, gravid abdomen. For pregnant TNGE people, these physiologic changes, coupled with changes from testosterone cessation, can exacerbate gender dysphoria [34]. Gender dysphoria is a feeling of distress or discomfort that some TNGE



In addition to the physical effects of pregnancy on the body, TNGE individuals also face the psychosocial challenges of navigating both the healthcare system and the world at large, as a pregnant person. One area of concern for pregnant TNGE patients is if and/or when to disclose their pregnancy status as it relates to their gender identity to clinicians and/or society at large [12]. A cross-sectional study of 10 transgender men who experienced pregnancy reported varying needs/desires for gender affirmation during their pregnancies [15]. Furthermore, they identified three main strategies for disclosing or concealing a pregnancy: pass a cisgender pregnant woman, pass a cisgender man, or present as a pregnant transmasculine person [15]. Participants varied which strategy they used throughout the duration of their pregnancies based on multiple factors such as the particular social setting, the people present, and the stage of their pregnancies [15].

TNGE people should be appropriately counseled about the physiologic and anatomic changes associated with pregnancy and discontinuing testosterone therapy. Additionally, they should be counseled on the risk of worsening dysphoria associated with these changes.

#### **Prenatal Care**

#### **Routine Prenatal Care**

Routine prenatal care for TNGE patients should follow the same standards of care used for their cisgender counterparts. Routine prenatal care can be provided by physicians and advanced practice providers including nurse midwives, nurse practitioners, and physician assistants. As previously stated, it is imperative to create a welcoming and inclusive care environment with healthcare providers who have specific knowledge and experience caring for TNGE patients [12, 13, 15], and this applies to the provision of routine prenatal care.

## **Options Counseling**

Prenatal care providers should assess for an intent and/or desire to continue or terminate any time a new pregnancy is diagnosed. TNGE patients can and do experience unintended pregnancies, with at least one study showing that 54% of pregnancies in a cohort of TNGE patients surveyed were unintended [6, 35]. In a different study by Light and colleagues, TNGE patients who had never used testosterone therapy were almost



three times more likely to have an unintended pregnancy than their peers who had used GAHT-T [32].

Full spectrum options counseling should be provided to all TNGE patients presenting with a new, unintended pregnancy. These should include continuing the pregnancy and terminating the pregnancy. For TNGE patients who desire pregnancy termination, services should be rendered or referrals should be placed in a timely and sensitive manner, taking care to remember that the decision on whether to continue or terminate a pregnancy is a deeply personal choice and clinicians should provide medically accurate, non-judgmental counseling and provide or help coordinate care for whatever option the patient chooses.

#### **Pregnancy Loss**

With pregnancy comes the risk of pregnancy loss. TNGE patients also experience pregnancy loss [6, 34, 36–38]. One study specifically looked at pregnancy loss in a subset of TNGE patients and identified several important patient-reported themes regarding pregnancy loss including that pregnancy losses can count as children, responses to pregnancy loss can range from devastation to relief, and lack of understanding from friends, family, and healthcare providers can make pregnancy loss more difficult [38].

Nearly 80% of all pregnancy losses occur in the first trimester [39]. ACOG provides excellent guidance on the management of early pregnancy loss in their "Practice Bulletin No. 200" [39]. This author endorses the ACOG practice bulletin and recommends providing this same standard of care to TNGE patients who experience pregnancy loss. Management of patients experiencing second or third-trimester pregnancy loss is beyond the scope of this article. This author recommends consultation with an obstetrician-gynecologist or other qualified obstetric care provider.

# **Intrapartum Care**

# **Routine Intrapartum Care**

Routine intrapartum care for TNGE patients should follow the same standards of care, guidelines, and best practices used for cisgender birthing patients. Again, special attention should be paid to ensure that the birthing space is inclusive and welcoming and that all providers involved with TNGE patients' intrapartum care are knowledgeable and experienced in caring for this population [12, 13, 15].

#### **Birthing Locations and Providers for TNGE Patients**

TNGE patients want to be involved in the decision on where to give birth [40]. Light and colleagues found that a

significant majority (78%) of TNGE patients in their cohort birthed in a hospital setting while the others birthed either at home (17%) or in an independent birth center (5%) [6]. Light et al. also found that TNGE patients reported using "non-physician providers and nonhospital birth locations more frequently than the general public" [6]. Some TNGE patients may prefer the midwifery model for intrapartum care due to its patient-centered, low-intervention approach to managing uncomplicated pregnancies [41]. Who will manage labor and where to birth are choices unique to each person and should be determined by the patient and guided by fetal and the birthing person's specific risk factors. Factors that may influence this choice include a provider's knowledge and acceptance of the patient's transgender identity [42].

# **Birthing Outcomes for TNGE Patients**

The data on birthing outcomes in TNGE patients are limited. Light et al. found that there was no difference in the pregnancy, delivery, or birth outcomes in TNGE patients who had previously used GAHT-T compared with those who had not [6]. Pregnancy complications in this study were selfreported by the participants, not verified by the investigators, and included hypertension, preterm labor, placental abruption, and anemia [6]. A greater percentage of TNGE patients who reported prior GAHT-T use had a cesarean birth compared to those with no prior use, although this was not statistically significant [6]. Of note, 25% reported the indication for their cesarean birth as being elective [6]. Stroumsa et al. found that identifying as transgender was not associated with significantly worse parental morbidity or preterm birth and was associated with a lower rate of cesarean birth [43]. Further research is needed on birth outcomes in this population.

## **Postpartum Care**

# **Routine Postpartum Care**

Routine postpartum care for TNGE patients should follow the standards of care, guidelines, and best practices for cisgender birthing patients. Discussions on contraception, lactation, and chest feeding as well as screening and management of postpartum mood disorders are part of routine postpartum care for all birthing patients. Special attention should be paid to these TNGE patients as they present unique challenges and opportunities in this patient population.

#### Contraception

Discussing contraception is an essential aspect of postpartum care. Postpartum TNGE patients are not excluded from this as their ability to conceive is established, and the



literature shows that unintended pregnancies can and do occur in this population [6, 35]. As previously mentioned, testosterone therapy should not be considered an effective form of contraception due to possible incomplete HPO axis suppression and breakthrough ovulatory events [31].

Light and colleagues found that in a survey of 197 AFAB individuals who self-identify along the masculine spectrum, 30 respondents (17%) reported using testosterone as a contraceptive method, and 10 respondents (5.5%) reported being told to do so by a healthcare provider [32]. Krempasky et al. note in their review of contraception across the transmasculine spectrum that prior concerns about increased risk of thromboembolic events in TNGE patients on GAHT-T and combined hormonal contraceptives (CHC) have not been substantiated and that their risk is similar to that of their cisgender counterparts [44]. To date, GAHT-T use has not been found to be a contraindication to any form of contraception [44]. Common concerns regarding contraceptive use in the TNGE community include possible dysphoric side effects and interactions between testosterone and hormonal contraception [44, 45]. Previous studies have shown that CHC do not prevent masculinization from testosterone and estradiol levels remain suppressed, as would be expected for TNGE on GAHT-T [44]. Postpartum TNGE patients should be assessed for other risk factors and counseled on all safe, available contraceptive options, including permanent surgical contraception via bilateral tubal ligation or salpingectomy.

#### **Postpartum Mood Disorders**

Rates of depression and suicide are higher in the TNGE community compared to the general population [10, 40, 43, 46]. TNGE patients may experience additional stressors in the postpartum period such as lack of support, difficulty accessing quality care, and discrimination within healthcare spaces [42]. In one study, 84% vs. 80% of postpartum TNGE patients screened positive for depression when using sensitive versus specific cut-off scores on standardized screening questionnaires [46]. Brandt and colleagues point out that the Edinburgh Postnatal Depression Scale (EPDS), a commonly used validated postpartum screening questionnaire, does not assess for factors that may predispose TNGE patients to postpartum depression such as worsening gender dysphoria [47]. There are no studies to date looking specifically at postpartum anxiety or psychosis specifically in the TNGE population. All postpartum TNGE patients should be screened for postpartum depression. Given the elevated risk in this population, additional touchpoints in the immediate postpartum period and ongoing through the first year after delivery may be helpful in identifying and treating postpartum mood disorders in a timely manner. Additional work is needed to create validated perinatal screening questionnaires for TNGE patients.



# **Lactation and Chest Feeding**

Postpartum TNGE patients will need to decide how they are going to feed their newborn. Some may choose formula or donor human milk, while others may choose human milk produced themselves [48, 49]. TGNE patients may choose to label breastfeeding using gender-neutral terminologies such as chest feeding, nursing, or mammal feeding [48, 49].

TNGE patients may experience challenges with chest feeding due to variations in the amounts of mammary tissue present, either from normal anatomic variation or as a result of certain chest masculinizing procedures [50]. Techniques and holds can be used to change the contour of the chest wall and improve latching [50]. Chest feeding may trigger dysphoria in some TGNE patients who have proposed coping strategies such as wearing multiple layers of clothing to hide enlarged mammary tissue or focusing on the functionality of the tissue [48]. Other interventions such as private pumping locations, wearing masculine clothing that facilitates easy chest feeding, and binding the chest intermittently may also help reduce feelings of dysphoria [49]. TNGE patients who wish to chest feed and choose to bind should only do so once their milk supply is well established and should use light pressure for short periods of time to avoid complications such as decreased supply and mastitis [48].

TNGE patients who choose not to chest feed should take steps shortly after delivery to reduce milk production such as only expressing milk when needed to relieve engorgement and using cool compresses to reduce pain and inflammation [50]. Some amount of milk production is to be expected if mammary tissue is present even if production is not stimulated [50].

Testosterone therapy has been shown to decrease human milk production [42]. Studies in cisgender women have shown that testosterone is not secreted significantly in human milk nor does it appear to have any short-term effects on neonates drinking said milk [42]. Current recommendations suggest deferring GAHT-T during chest feeding [42]. A recent case report documented the initiation of GAHT-T in a lactating TNGE patient and found no adverse effects in the infant during the 5 months of chest feeding with therapeutic parental testosterone levels [51••]. Additional research is needed to determine safe protocols for GAHT-T while lactating.

#### **Restarting Testosterone Postpartum**

TNGE patients may wish to start/restart GAHT-T in the postpartum period [16]. There are no current guidelines outlining the optimal timing for restarting GAHT-T. The

decision on when to restart should therefore be made in a shared capacity between the TNGE patient and the prescribing physician and should take into consideration the patient's chest-feeding status. It may be reasonable to defer initiation until at least 6 weeks postpartum as there is a physiologic state of hypercoagulability in the immediate postpartum period. Future studies should be dedicated to determining an optimal minimum time after delivery when GAHT-T can be safely restarted.

#### **Conclusions**

The TNGE patient population is rapidly increasing in the United States [1]. Many of these patients will have questions regarding fertility, fecundity, and childbirth. There are currently few, if any, standardized practice guidelines or recommendations for the provision of pregnancy care in TNGE patients. Common themes across the available literature focus on the need for knowledgeable, welltrained providers and welcoming, inclusive care environments. Pregnant and birthing TNGE patients require special consideration during routine prepregnancy, prenatal, intrapartum, and postpartum care in addition to the standard care that their cisgender counterparts receive. Much of the available literature is limited by small sample sizes, qualitative/mixed method study designs, convenience sampling, and poor generalizability to the broader TNGE patient population. Future research endeavors should focus on objective, larger-scale studies to help develop standardized perinatal care guidelines.

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**Data Availability** No datasets were generated or analysed during the current study.

# **Compliance with Ethical Standards**

Conflict of Interest The authors declare no competing interests.

Human and Animal Rights and Informed Consent All reported studies/ experiments with human or animal subjects performed by the authors have been previously published and complied with all applicable ethical standards (including the Helsinki Declaration and its amendments, institutional/national research committee standards, and international/national/institutional guidelines).

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