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Administering drugs to an individual in a non-pathological situation: The Caster Semenya case

JAGADEESH N

Abstract

The International Association of Athletics Federations (IAAF) has barred individuals whose circulating testosterone levels are higher than 5 nmol/L from competing in women's competitions in middle-distance track events. To become eligible, they must take anti-testosterone treatment to achieve the appropriate testosterone levels. The 2019 decision of the Court of Arbitration for Sport has brought the spotlight back on Caster Semenya's case and on the ethics of testing the testosterone levels of sports persons with or without consent, imposing anti-testosterone treatment in order to qualify to participate in sports competitions for females. This article debates all the issues concerned from various perspectives.

Keywords: Testosterone levels, intersex variations, DSD, IAAF rules, sex verification tests, anabolic effects.

Background

Caster Semenya is a South African Olympic athlete who was asked by the International Association of Athletics Federations (IAAF) in 2009 to undergo sex verification tests to prove herself female. She was prevented from competing in world athletics events till the IAAF deemed her eligible to compete in 2010. The Caster Semenya case is in the news again (1); but this time the medical community is also involved in the debate. The Court of Arbitration for Sports (CAS) upheld the IAAF regulation (1,2, 3) that individuals must have testosterone levels below 5 nmol/L to compete as females. Otherwise, they

must take treatment to lower their testosterone levels. This brings us to a debate on several ethical issues.

What is the available research evidence on the issue of testosterone levels and their impact in sports persons having DSD (Differences in Sex development)?

Testosterone levels improve individuals' anabolic effects, muscle building abilities, and confidence levels (4). Whenever there are higher levels of circulating testosterone in a female with properly functioning androgen receptors, there is a definite increase in muscle mass and muscle strength, circulating haemoglobin levels, and thus, sporting potential (3). Hence, IAAF has restricted the eligibility to compete in women's competitions based on circulating testosterone levels to remove any unfair advantages in the 400 m to one mile middle distance track events (5). It also specifies waiting for a six-month period after the administering of anti-testosterone treatment to remove any residual effect of the high testosterone levels (2,3) in sports persons with DSD.

Are all individuals with DSD or hyperandrogenism barred from all sports competitions?

As per IAAF guidelines, individuals with differences in sex development (DSD) or hyperandrogenism are not barred from all sports competitions. The IAAF has clarified (2) that only for international competitions, individuals with the following DSD are barred from competing in the female category in distance track events (400 m to a mile distance) in both individual and relay competitions: 5 β -reductase type 2 deficiency, partial androgen insensitivity syndrome (PAIS), 17 β -hydroxysteroid dehydrogenase type 3 (17 β -HSD3) deficiency, ovo-testicular DSD, any other genetic disorders involving disordered gonadal steroidogenesis. In addition, to be barred, individuals with DSD should have circulating blood levels of testosterone above 5 nmol/L and sufficient androgen sensitivity for the testosterone levels to have a material androgenising effect. Female athletes exhibiting hyperandrogenism (polycystic ovarian syndrome and androgen insensitivity syndrome) (3) are not barred, as their circulating blood levels of testosterone are below 5 nmol/L. This standard of 5 nmol/L could be because of IAAF

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findings (2) of increased muscle bulk and power as a result of high testosterone levels. If such individuals are allowed to compete in female events, it would be unjust and unfair as the other competing females may not have the same advantages of increased blood testosterone levels (2)

Various counter-arguments to the IAAF position have been presented:

- Once individuals are categorised or grouped (for instance, as female), there should not be any discrimination amongst members of the group based on characteristics that are not induced (intentional or accidental) and are congenital (that they are born with), genetic (hereditary), or over which the individual had no control (6, 7).
- The World Medical Association claims that such testosterone levels in individuals with DSD are due to genetic variations, and any attempt to reduce those testosterone levels (which is not pathological) would amount to a violation of international medical ethics (beneficence, non-maleficence, and autonomy) and human rights standards (discrimination on body status, violation of right to life, liberty, security of person, forced treatment, and leave them without any alternative options) (8). In addition, such efforts to reduce testosterone levels are harmful to the individual.
- The South African Medical Association has argued that the IAAF regulation is based on a single flawed study and does not conform to standards of scientific rigour, medical ethics, or evidence-based practice (9).
- A fourth counter-argument is that we are not able to distinguish with certainty the urinary metabolites of exogenous origin testosterone and endogenous origin testosterone, and thus, false positives are possible. Hence, asking someone to reduce their testosterone levels (over which they have no control) when current medical science cannot pinpoint whether the (individuals with DSDs) fault would be against the principles of natural justice (4).

Is it ethical for a medical practitioner to administer anti-testosterone drugs to an individual in a non-pathological situation?

All medical practitioners are required to act for the benefit of the patient and, at the least, cause no harm to the patient while they administer care. The questions now are: Given this IAAF regulation, if practitioners administer anti-testosterone drugs (1,2,3) to sportspersons in non-pathological conditions, are they violating the ethical principles of beneficence and non-maleficence? Medical practitioners cannot forcibly treat individuals without their informed consent. Do doctors working in government-run sports academies have a greater duty towards the academy/government or the individual sportspersons? Can societies, governments or regulatory bodies force treatment on sportspersons just because they are representing the nation? In reality, sportspersons are forced to undergo treatment to lower their testosterone levels due to

pressure from their team members, coaches, administrators, and governments for the sake of fame, national pride, and recognition.

Medical practitioners, are ethically (10) duty-bound to treat only the sick and injured. Here, the sportsperson is neither sick nor injured to require treatment with anti-testosterone drugs. If it is argued that medical practitioners acting as clinicians (11) must provide promotive healthcare apart from curative, preventive, palliative, and holistic care, the counter-argument would be that administering anti-testosterone drugs cannot be promotive healthcare if it is contrary to the interests and consent of the person being treated. Further, inflicting the ill effects (short term and long term) of anti-testosterone drugs on a healthy body cannot be termed promotive healthcare, which the World Health Organization defines as improving quality of life (12). The harmful effects of anti-testosterone drugs include hot flashes, tiredness, anaemia, loss of skeletal muscle mass, sexual dysfunction, infertility, bone loss, bone fractures, cardiovascular diseases, memory loss, mood changes including emotional instability, and depression, among others.

Can sex-reassigned individuals participate in sporting events of their choice?

Not all sex-reassigned individuals can participate in sporting events immediately after their surgery as per IAAF regulations. Individuals undergoing female-to-male sex reassignment can participate in all male events provided that their sex identifying certificate and legal documents (passport) are in order. The IAAF regulations explain that this is because they would be competing with males who have higher physical strength and stamina. But individuals undergoing male-to-female sex reassignment will be eligible to participate in female events only 12 months after their sex reassignment surgery, and only if their circulating blood testosterone levels are below those specified for female competitions, as they would be competing with females who have lower physical strength and stamina (2,13,14). This waiting period of a year is to remove all the effects of high levels of testosterone. However, the scientific rigour of the research underlying the IAAF regulations has come under question. Can a one-year waiting period nullify the advantages, if any, that a male-to-female sex reassigned athlete would have gained by competing in female events immediately? Definitely not, since the IAAF regulations require the circulating blood testosterone levels to be less than 5nmol/L even one year after the sex reassignment surgery.

Are statements and official positions held by medical bodies of no value in legal discourse?

IAAF is the supreme global body for athletics regulations, and its regulations are binding on all national athletics federations (2). But, in the Caster Semenya case, the World Medical Association has urged physicians across the globe (114 national medical associations) not to follow the IAAF regulations. It has reminded physicians that administering anti-testosterone drugs in a non-pathological condition is

against medical ethics and that artificially modifying blood constituents, biochemistry, or endogenous testosterone is harmful to the individual (8). Similarly, the South African Medical Association has urged the IAAF to review its stance, claiming that the science it has used is flawed (9). It has called for better and more extensive scientific research on this contentious issue. In response, the IAAF has published all its evidence in the public domain and has urged the World Medical Association to revise its stand based on this evidence (15). It claims that its stand is based on scientific literature spanning 15 years and observations from the field. What matters in the legal battle is, of course, the evidence. In May 2019, the IAAF convinced CAS to uphold its regulations on the basis of its scientific evidence (2). Caster Semenya exercised her right to appeal to the Swiss federal courts within 30 days, challenging the IAAF stand. On appeal, the Swiss Supreme Court suspended the IAAF regulations on testosterone levels with immediate effect, giving relief to Caster Semenya until June 2019 (16). In July 2019, the Swiss Supreme Court reversed its previous judgement and decided in support of the IAAF ruling; and now Caster Semenya is again not allowed to run in 400m to one mile distance events in Olympic and World championships (17).

Can you test for testosterone levels without informed consent?

The IAAF has clarified that informed consent is mandatory for all three levels of hormone examination and testing (2), and that the athletes have to volunteer their blood and urine samples for testing testosterone levels by gas or liquid chromatography and mass spectrometry. However, there are rumours that in Caster Semenya's case in 2009, Athletics South Africa (1) secretly tested for gender. This violates the ethical principle against forcibly testing an individual for any medical parameter unless a law permits it (this is also true for certain crimes in certain countries) (18). Sex verification tests have also undergone sufficient modifications over time (19). Hence, informed consent must be obtained from athletes after explaining diurnal variations in testosterone levels and possible variations in the level caused by training, exercise, and competitions. The difficulties in distinguishing the metabolites of exogenous and endogenous testosterone also have to be discussed (4), like the testosterone to epitestosterone glucuronides ratio, carbon isotope ratio detection for exogenous testosterone administration and androstenediol, androstenedione, dehydroepiandrosterone (DHEA), dihydrotestosterone detection for endogenous testosterone administration.

What is the available research evidence on the issue of testosterone levels and their impact in sports persons having DSD?

The naturally occurring level of testosterone in most females is 0.12–1.79 nmol/L (20), while after puberty, the testosterone levels in males is 7.7–29.4 nmol/L. Only females with DSD or a tumour will have serum levels of testosterone of 5 nmol/L

and above (21). In cases of DSD, the level of circulating testosterone in females may be more than the male range. There are many research studies that show that if an individual is sensitive to androgen receptors and the androgen receptors are functioning normally, then high levels of circulating testosterone increase haemoglobin levels, increase muscle mass and muscle strength, and improve their sporting potential (21–28).

The ergogenic advantage is about 9% when individuals have circulating testosterone levels of the male range rather than the female range (21). Another study found that female athletes with high FT (free testosterone) levels have a significant competitive advantage over those with low FT in 400 m, 400 m hurdles, 800 m, hammer throw, and pole vault (5).

Contrary research evidence is also available, showing that though ergogenic effects are associated with exogenous androgens, there is no clear evidence of any competitive advantage in cases of endogenous hyperandrogenism like in congenital adrenal hyperplasia, DSD, and polycystic ovarian syndrome (29).

Are the researchers being gender insensitive or discriminatory?

Caster Semenya's allegation is that the IAAF's stand is discriminatory, their regulations have been framed to disqualify her, and that their researched evidence is biased (2). On the other hand, IAAF claims that they maintain the athlete's privacy and confidentiality during the tests and seek informed consent. They are the chosen athletics ombudsmen (2) working for athletes. There are now medical journals insisting that researchers comply with gender disaggregated data and gender based analysis (accepted characteristics/attributes of male and female gendered identity) in their research (30, 31). There are enough gender toolkits to help researchers avoid being gender insensitive or discriminatory in their research (32). Researchers first conduct a gender analysis to identify qualitative and quantitative differences in their subjects and to address gender parities. Through gender sensitive monitoring, evaluation and stakeholder meetings knowledge on gender issues is shared. Conducting multiple, long-term research studies at many centres with large sample sizes and using these gender toolkits may address the concerns raised in the Caster Semenya case.

If administering banned drugs to enhance performance in sports is doping, then what should we call administering drugs to decrease performance in sports?

This question is especially relevant since such drugs are forced on athletes, their autonomy is compromised, and they are forced to choose between their career and ensuring that their rights are not violated. The question remains, should we administer anti-testosterone drugs in a non-pathological condition? Are the effects of naturally available testosterone along with the long-term effects of malignancy to be taken

into account before mandating that the DSD individual must consume anti-testosterone drugs? There is a need to provide athletes adequate counselling on the short-term gains and long-term impacts of these drugs. How do we justify the harmful effects of anti-testosterone drugs like infertility, mood changes, and cardiovascular diseases?

Is too much scientific evidence impacting and interfering with how sports are played?

Yes, today scientific evidence hugely impacts different aspects of sports, whether it is training, performance enhancement, injury prevention, or recovery. The IAAF has a dedicated health and science division that advises on all aspects of training, performance, injury prevention, and general health. Even players practising fasting (for example, Muslim players observe roza in the holy month of Ramzan) are given advice on the type of diet to be consumed, fluid management, and fitness and exercise.

Due to the prevalence of doping, there has been much scientific research on detecting and preventing this malpractice. We have scientific ways of detecting the use of banned drugs and substances by testing various body fluids. Other areas where scientific evidence has had great impact are age estimation, detecting DSDs, and sex identification. However, research evidence from scientific studies that are peer reviewed and widely accepted are the need of the hour to convince all stakeholders.

Are today's sports played with sportsmanship and fairness?

Sportsmanship is an important attribute of sports. It refers to fair, polite, ethical, and appropriate behaviour exhibited by sportspersons while playing sports. However, there are now debates on whether the person who first crossed the finish line actually won, when sportspersons do not fit a binary sex identity, exceed the age range, or consume banned performance-enhancing drugs or chemicals. The IAAF argument that regulations (2) ensure fairness in female competitions needs to be taken with a pinch of salt. There are several genetic traits that give sportspersons an advantage, such as increased height (in basketball), wider arm span (swimming), more lung capacity (athletics, etc), but sports bodies and regulators are silent about them. Is it fair to restrict sportspersons based on one genetic abnormality (like DSD) while allowing other genetic abnormalities that give individuals physical advantages?

What is the status of sports medicine, both globally and in India? Is quality research being conducted in the field?

Sports medicine is an upcoming field in medical science. It is a multidisciplinary field covering curative, rehabilitative, and preventive aspects of competitive and recreational sports. The purpose of sports medicine is to maintain sportspersons' health, fitness, and strength; and prevent and treat injuries

based on continuous research. It helps players perform consistently by increasing their maximum capabilities without consuming any drugs or banned substances. There are a few such specialists in developed countries, but the Indian scenario is not encouraging. There are few doctors opting for sports medicine, which is why the research in this arena is poor and limited. So, policymakers have to rely on the limited available research. Similarly, in the case of DSDs, we are stuck with limited research that is peer reviewed, widely accepted, evidence-based, and in compliance with medical ethics and legal standards. Sports medicine specialists should conduct research in multiple countries with large samples to test whether individuals with DSDs playing sports in general, and athletics in particular, have any undue advantage because of their genetic abnormality. Unfortunately, in India, the few specialists are too overburdened with curative and rehabilitative work to be involved in research.

Conclusion

The IAAF regulations regarding the testosterone levels of female athletes have opened up a debate about doctors administering treatment to athletes in non-pathological conditions. In this case, one can argue that the medical principles of beneficence, non-maleficence, and autonomy are compromised. Medical associations have issued policy statements, taking different stances on the issue. The doctors involved must now exercise their choice, while balancing ethics, legal requirements, and scientific evidence.

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The ethics of penal amputation

ANJAN K DAS

Abstract

Malaysia is a South East Asian country with a racially diverse population. Islam is the state religion and about 60% of the population is Muslim, but the rights of other religious groups are

protected by law. The Parti Islam se Malaysia, which has ruled the state of Kelantan since 1999, and believes that Malaysia should be ruled by Sharia law, recently proposed the implementation of Hudud laws in Kelantan. However, the federal government has ruled out its implementation. The suggestion stirred up a controversy among the physician community and the Malaysian Medical Association rejected a proposal by the state's political leadership to utilise the services of qualified surgeons to carry out punitive limb amputations. Several Islamic states such as Sudan, Saudi Arabia, and Iran practice Islamic penal justice, including amputations. The question therefore arises: how should a modern medical practitioner approach this ethical question? This study focuses mainly on Malaysia, but draws upon practices in other Islamic countries also.

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