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Research Paper

Participation of transgender and gender diverse persons in cardiovascular clinical trials

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ABSTRACT

Study objective: Transgender persons face increased risk in developing cardiovascular diseases due to administration of hormonal therapy used for gender expression, or due to the presence of other risk factors, such as minority stress and difficulty to have full access to health care. Even though the need for gender diversity in research has been identified, the number of clinical trials including transgender persons remains low. The aim of this study was to highlight gaps in inclusion of transgender individuals in cardiovascular clinical research.
Design, setting: A search in the pubmed.com database, as well as in the clinicaltrials.gov repository, was performed with search terms regarding transgender persons and cardiovascular diseases.
Main outcome measure(s): The inclusion of transgender persons in cardiovascular clinical trials was evaluated.
Results and conclusions: This study revealed that there is only a small number of cardiovascular clinical trials including or studying transgender persons. This finding demonstrates the overall lack of clinical trials regarding cardiovascular health in transgender individuals and is indicative of their under-representation in clinical research.

1. Introduction

Transgender persons are those whose gender identity does not correspond to the sex that was assigned to them at birth [1]. Sex is defined by chromosomal composition, hormonal function, genitalia form and is usually identified as male or female, while gender identity refers to social constructs, roles, behavior patterns and self-identity definition of a person; therefore, there are various gender identities that one can be identified as [2]. However, both sex and gender affect human health from a biological and a social aspect [3–5]. In fact, the interaction between sex and gender has a great impact on human health and wellbeing, since both affect and are affected by environmental risk factors, behaviors that can increase disease risk and progression, access to health care systems, treatment outcome and disease prevalence [6–22]. Additionally, the effects of pharmaceutical agents can vary in different people, both in terms of adverse effects and therapeutic benefit [23–25].

Currently, 0.5 % of the population in the USA [26,27] and 0.6–1 % of the population in Europe identify themselves as transgender [28,29], and there is a continuing growth of the transgender population. However, the inclusion of transgender persons in medical research is limited. The scientific community identified the need to increase gender diversity in research, leading to the publishing of the Sex and Gender Equity in Research (SAGER) guidelines, thereby addressing sex and gender inequity in medical research [30].

Many transgender persons experience gender dysphoria and seek to obtain medical help for gender expression. A primary way is by gender-affirming hormone therapy (GAHT), thereby modifying their secondary sex characteristics and/or their genitalia. During this therapy, they receive either androgens in order to increase masculine characteristics or estrogens combined with androgen suppressors in order to increase feminine characteristics [31]. GAHT can improve the psychological situation of these individuals by repressing gender dysphoria, but it can also have adverse effects, including increasing cardiovascular risk and complications [32–35]. With cardiovascular diseases being the number one cause of morbidity and mortality worldwide [36,37], it is important to consider and better understand the effects of GAHT in transgender persons.

Furthermore, transgender persons may face different or increased cardiovascular risk factors compared with the general population, due to

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increased stress levels (e.g. minority stress), difficulties in accessing health care systems and socio-economic factors [38–40]. Overall, there is a lack of big cohorts and of international cohorts including transgender people in clinical trials [38,41,42]. However, this is important so as to better understand cardiovascular risk and to improve cardiovascular health in transgender persons. The aim of the present study was to assess the inclusion of transgender persons in cardiovascular clinical trials, in order to examine and highlight major gaps.

2. Materials and methods

2.1. Study design/data collection

Published data were searched employing the PubMed database with keywords being defined as "transgender persons", "transgenderism", "cardiovascular diseases" with or without the application of the "clinical trial" filter. Furthermore, a search of registered clinical trials was performed employing the ClinicalTrials.gov database with the same keywords.

3. Results

3.1. PubMed

Searching PubMed with the terms "transgender" and "cardiovascular diseases" revealed 222 articles, spanning from 2006 to 2023, with 66 of these articles being review articles and only 2 of them being clinical trials; interestingly, these 2 articles were referring to the same clinical trial, i.e. the REPREIVE trial about HIV infections [43]. Repeating the search using the terms "transgenderism" and "cardiovascular diseases" revealed 101 articles, spanning from 1968 to 2023. Among those, there were 24 review articles but only 2 clinical trials, with one of them being the REPREIVE trial previously mentioned. When the search terms "transgender women" and "cardiovascular" were used, 143 articles were found on PubMed. Forty of them were review articles and 3 were clinical trials, while when the term "transgender men" was used, only one additional clinical trial was found. The search term "transsexualism" revealed 87 articles, with 25 being review articles and 5 clinical trials from 1989 to 2023. Furthermore, many of these articles were common among different searches, revealing a total of about 80 articles on transgender persons that have been published in the field of cardiovascular diseases. It is noteworthy that clinical trials in this field were not published any time prior to 2006 (Fig. 1).

3.2. ClinicalTrials.gov

Searching ClinicalTrials.gov with the terms "condition: cardiovascular diseases" and "other terms: transgender persons" retrieved 62 results with only 6 of them actually being clinical trials about cardiovascular diseases in transgender persons. These 6 clinical trials, 9.7 % of the retrieved results, that include transgender persons had the following characteristics: 3 were still running; 2 of them were being conducted in the USA and 1 in Denmark; 1 that took place in Brazil and was complete; 1 with only 6 persons registered in the trial was terminated as decided by the Institutional Review Board of the institution where the trial took place; the last one was withdrawn due to not receiving any funding (Table 1). Repeating the search with the terms "condition: cardiovascular diseases" and "other terms: transgenderism" retrieved 3 results (Table 1). Two of them were conducted in Europe and were actively recruiting and the other one was terminated. When the search terms "cardiovascular diseases" and "transgender men" were used, only 2 out of 9 trials were of relevance (Table 1), while when "transgender men" was replaced with "transgender women", 42 trials were found, with only 3 out of 42 trials examining cardiovascular diseases in transgender persons (Table 1). Finally, when the term "transsexualism" was used, 3 clinical trials were revealed that were already included in the results of previously used search terms.

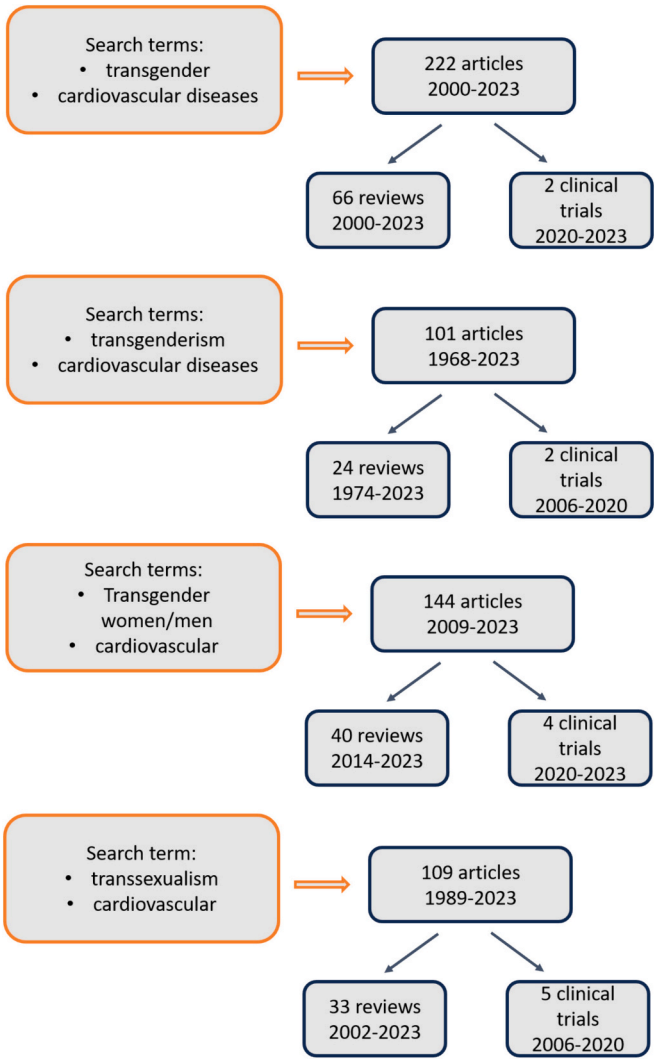

Fig. 1. Search results from Pubmed.com using search terms: *"transgender and cardiovascular diseases"* or *"transgenderism and cardiovascular diseases", "transgender women/men and cardiovascular" and "transsexualism and cardiovascular".*

4. Discussion

The present study shows that transgender persons are still widely underrepresented in cardiovascular clinical trials, even though both the percentage of persons identifying as transgender and the percentage of transgender persons that receive GAHT are increasing. A less than 10 % inclusion in cardiovascular clinical trials indicates that the cardiovascular health of this group of individuals is not assessed properly, even though they are identified as high-risk patients for cardiovascular disease [38]. Furthermore, a limited focus on mainly the effects of GAHT as a factor of increased cardiovascular risk is somehow underestimating the overall problem. The increased minority stress levels and other social determinants of health, such as victimization and marginalization, along with mental health issues, depression and others [44], which are present in transgender individuals for a long period of time, can act as risk factors for cardiovascular diseases, such as hypertension and dyslipidemia [45,46].

Additionally, the fact that less than 1 % of the studies published regarding transgender persons and cardiovascular diseases are clinical trials could be an indication that despite having identified the need for increased and modified cardiovascular care for such individuals,

Table 1
Clinical trials retrieved from ClinicalTrials.gov using search terms: "*condition": cardiovascular diseases* and "*other terms": transgender persons, transgenderism, transsexualism, transgender women, transgender men.*

Clinical trial ID	Title	Location	Status
NCT04254354	Transgender Men, Non-binary Persons and Testosterone Treatment BODY IDENTITY CLINIC	Denmark	Running
NCT04128488	Effects of Gender-Affirming Hormone Therapy Among Transgender Women	Boston, USA	Running
NCT06043310	Estrogen and Microvascular Function	Wisconsin, USA	Running
NCT01620398	Brazilian Cardioprotective Nutritional Program Trial	Brazil	Complete
NCT05387577	Coagulation and Fibrinolysis of Estradiol in Transwomen	Wisconsin, USA	Terminated Per MCW IRB
NCT04922424	Mechanisms and Interventions to Address Cardiovascular Risk of Gender-affirming Hormone Therapy in Trans Men	Connecticut, USA	Withdrawn (lack of funding)
NCT04838249	Effects of Cross-sex Hormone Therapy on Eating Behavior, Metabolism, Energy Balance and Cardiovascular System	Germany	Recruiting

appropriate measures in order to minimize such inequities are still lacking. Furthermore, socio-economic aspects could be an obstacle to the inclusion of transgender persons in cardiovascular clinical trials [47]. However, previous studies have also highlighted the lack of commitment to the SAGER guidelines [30] and those of the Measuring Sex, Gender Identity and Sexual Orientation report [48] that were published in order to help researchers to record and report sex and gender identities in clinical research [41].

Furthermore, the use of terminology, such as transgenderism, which is an old term that has been first introduced by Virginia Prince (1912–2009) in order to describe both transsexualism and transvestism [49], cannot describe the difference between the sex assigned at birth and the gender identity and expression of transgender persons. Importantly, some of these terms are even considered transphobic. Therefore, the fact that database search engines still include such terms, or even more, the fact that researchers still use such terminology in order to describe their studies is indicative of the progress that needs to be made in the future in order to identify and address cardiovascular health issues that may arise in transgender persons.

4.1. Conclusions

As the number of individuals that are transgender is increasing, there is a clear need to expand the inclusion of transgender persons in cardiovascular clinical trials. The cardiovascular impact of both the health stressors induced in transgender persons and the GAHT that is administered to treat gender dysphoria are considered risk factors of cardiovascular complications. Therefore, it is necessary to increase in the future the participation of transgender persons in cardiovascular clinical trials. In order to achieve such an increased inclusion, both the research community and transgender persons need to be more informed about the cardiovascular risks that these individuals face or will probably have to deal with in the future. The role of cardiovascular societies and national or international organizations, along with health practitioners, could be of great importance in increasing awareness and inclusion. Even though such an effort could be a long-term goal, it would lead to positive health and socio-economic impacts.

CRediT authorship contribution statement

Rodopi Stamatiou: Writing – original draft, Visualization, Investigation, Formal analysis. **Georgios Kararigas:** Writing – review & editing, Validation, Supervision, Conceptualization.

Declaration of competing interest

None If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Declaration of Generative AI and AI assisted technologies in the writing process

Statement: During the preparation of this work the authors did not use any Generative AI or any AI assisted technologies in the writing process.

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