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Review article

# Sex and gender gap in spinal cord injury research: Focus on cardiometabolic diseases. A mini review

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ABSTRACT

Cardiometabolic disease (CMD) is among the leading causes of morbidity and mortality in people with a spinal cord injury (SCI). Despite well-acknowledged sex and gender differences in CMD in the general population, they remain insufficiently studied in persons with SCI. To describe the landscape of sex and gender in SCI research, we searched the literature for systematic reviews on cardiometabolic health in this population. Out of 15 systematic reviews identified, only 9 provided meaningful information on sex. Although one-quarter to one-fifth of the SCI population is female, women comprised only one-eighth to a quarter of study participants. A number of clinical studies purposively excluded women, to make the study population more homogenous. For those studies which included both sexes, in general, no sex-specific analyses were performed due to small sample sizes. All these reasons have contributed to the underrepresentation of females in the current body of evidence. Therefore, future studies should adopt a more sex- and gender-sensitive research framework to address cardiometabolic risk in SCI. Novel and advanced epidemiological methods should also be used, considering small sample sizes. Finally, collaborative research (through consortia and multi-center studies) should be encouraged to include more females. More inclusive research will ensure that everyone will benefit from scientific advancements, regardless of sex and gender.

## 1. Cardiometabolic risk following the spinal cord injury

Spinal cord injury (SCI) is a debilitating condition that renders a person with a lifelong disability and leads to overall health impairment. SCI occurs in approximately 485 cases per million inhabitants and causes a significant burden to the healthcare system because of its chronicity. Men tend to be injured at an earlier age in comparison to women and present around 80 % of the overall cases [1].

Although the majority of SCI cases are male, there are clear sex and gender disparities in the injury pathogenesis, neurological recovery and other important health outcomes. [2] Sex refers to biological and physiological characteristics between males and females, while gender is a socially constructed definition of the roles and identity between the opposite spectrums. SCI rehabilitation programs are tailored according to these anatomical and physiological differences, including different pain thresholds and psychosocial status that are suggested to be sex-dependent. However, with the improvement of medical care and prolonged life-expectancy in SCI individuals over the past two decades, the research focus shifted from neurological recovery and rehabilitation to secondary health conditions such as pain disorders, pressure ulcers, urinary tract infections, cardiometabolic diseases (e.g. cardiovascular diseases, diabetes, obesity), and other chronic diseases of aging. [3,4] These are often atypical and develop prematurely (20–25 years earlier) in comparison to the able-bodied population as a consequence of accelerated functional and metabolic decline after SCI [5,6], Fig. 1.

In persons with SCI, the prevalence of heart disease is 17.1 % (ages 65–69 years) compared with 4.9 % (ages 65–69 years) for individuals without SCI, while the odds of heart disease or stroke are more than two and three-folds greater in individuals with SCI in comparison to individuals without SCI, respectively. [7,8] Cardiovascular complications are, therefore, among the leading causes of death in persons with SCI and an important determinant of longevity and quality of life in this vulnerable population [9–11]. Thus, there is an emerging need to improve research in this area. Men have a higher risk of cardiovascular

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disease (CVD) than women in the general population [12,13]. Women, however, have a different trend— the cardiovascular risk of women changes across their reproductive stage. Women experience variations in the sex-specific hormones (i.e., sex steroids and their derivatives) and iron metabolism around the menopause onset. These changes may affect their body composition, serum lipid profile, glucose metabolism, blood pressure regulation, and coagulation system, which alters the risk of developing type 2 diabetes and CVD. In SCI, increased CVD risk has been linked with autonomous dysfunction, glucose intolerance, dyslipidemia, blood pressure dysregulation, physical inactivity, poor diet, and prolonged inflammatory stress [9]. These metabolic changes may be of particular interest in women during menopausal transition as their metabolic profile worsens independent of the injury and women with SCI may reach menopause earlier in comparison to their able-bodied peers [14].

Considering that SCI population is predominantly male, in this mini-review, we searched the literature to determine the landscape of cardiometabolic health research in the SCI and the sex/and gender representativeness across the relevant evidence.

## 2. Methods

The MEDLINE (via Ovid) was searched to identify systematic reviews and/or meta/analysis (of interventional and observational studies) investigating cardiometabolic health outcomes in individuals with SCI. A search was performed from inception until 22$^{nd}$ May 2020 without date and language restrictions and using the terms related to SCI (i.e., *spinal cord injuries*, *paraplegia*, and *quadriplegia*) and cardiometabolic diseases (i.e., lipids, glucose, blood pressure, and inflammation). Systematic reviews focusing on dysautonomia and orthostatic hypotension were not considered for inclusion. Detailed search strategy can be found in the **online Supplement**.

## 3. Gender reporting gap in spinal cord injury research

We identified 15 systematic reviews focusing on cardiometabolic health in SCI (Fig. 2, Table 1), of which five reviews provided no meaningful information on sex/gender distribution among the study participants [15–19]. In a meta-analysis of 17 observational studies exploring serum lipid levels, only 7 studies reported data for females with a cumulative population of 1,603 males and 271 females [20]. Similarly, in another review on carbohydrate and lipid disorders, the majority of study participants were male, and even in studies that appeared to include both men and women, the lipid values were mostly not reported by sex [21]. In a large review including 98 studies and exploring the influence of the neurological level of SCI on blood pressure, 78 % of studies reported sex of study participants and among those studies males accounted for 91 % of the study population while authors found no studies focusing exclusively on female SCI individuals [22]. In a meta-analysis to explore leptin concentration changes in SCI individuals, five included studies were conducted only in males to omit the effect of sex hormones on leptin levels [23].

The remaining six reviews were focused on the beneficial role of physical activity and exercise on cardiometabolic health of spinal cord injured individuals. In an extensive review on the effects of exercise on fitness, cardiometabolic health, and bone metabolism, the evidence for different outcomes were primarily based on information from young and middle-aged men (across the outcomes percentage of men varied from 45 % to 80 %) [24]. In another review to determine the effectiveness of exercise in improving carbohydrate and lipid metabolism disorders, the percentage of male-only population ranged from 51 % to 88 % depending on intervention type [25]. Similarly, the male predominance was also observed in the remaining four reviews of observational and interventional studies on exercise/physical activity role in endocrine risk modification in SCI individuals [26–29].

Across included systematic reviews, some original studies provided sex-stratified analyses, showing inconsistent results. A cross-sectional study of 112 SCI individuals (32 premenopausal women and 80 men within the same age range) showed that women with SCI in comparison to men, had a more favorable lipid profile [30]. Similarly, in cross-sectional study comparing serum lipid profiles in 320 subjects with SCI and 303 relatively sedentary able-bodied controls, men, but not women with SCI, had lower high density lipoprotein values in comparison to controls [31]. In addition, men with SCI had a higher degree of insulin resistance compared to women with SCI [32]. Yet, in female-specific study comparising 42 women with SCI and their race-, body mass index-, and age-matched able-bodied controls, no differences in fasting glucose metabolism were observed between SCI and able-bodied women. However, there were some indications for differences in oral glucose tolerance test, with tetraplegic women having a poorer response in comparison to able-bodied and paraplegic women [33]. A small study comparing CVD risk profile among 11 pre- and 6 postmenopausal women with SCI, reported similar trends in some risk factors as seen in able-bodied women. In particular, triglycerides, total cholesterol and low density lipoprotein being increased in post- in comparison to premenopausal women, while no differences were seen in blood pressure, body mass index and glycemic indices [34]. Yet, studies focusing on clinical CVD outcomes were mostly conducted in males [35, 36]. In a cohort with a 17-year follow-up, women had a greater rising incidence of cardiometabolic syndrome at follow-up in comparison to men, however this difference was not statistically significant (only 26 women were included) [37]. Authors often suggested that, similar to

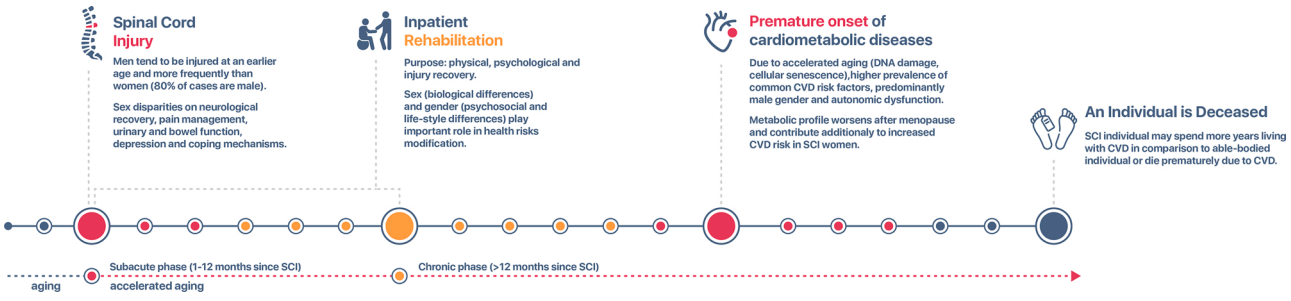


**Fig. 1.** Sex and gender differences underlying increased cardio-metabolic risk following spinal cord injury.
Spinal cord injury (SCI) occurs predominantly in males (80 % of cases), and as such, much is less is known on the disease process, prognosis, and complications in women. SCI has been linked with autonomous system and liver dysfunction, rapid changes in body morphology (loss of bone and muscle mass and increase in fat mass), hormonal (sex steroids and cortisol) and metabolic changes (glucose intolerance, dyslipidemia) and prolonged inflammatory stress. Cardiovascular diseases are nowadays suggested as the leading cause of death in SCI individuals and biological (sex) and socioeconomic and lifestyle (gender) differences are important in modifying health risk in both able-bodied and SCI population. However, relatively small numbers of subjects, inadequate controls for confounding variables, diverse study populations, and male predominance in SCI research contributed to considerably low quality of evidence in cardiometabolic risk assessment after the SCI and evident research gap in women.

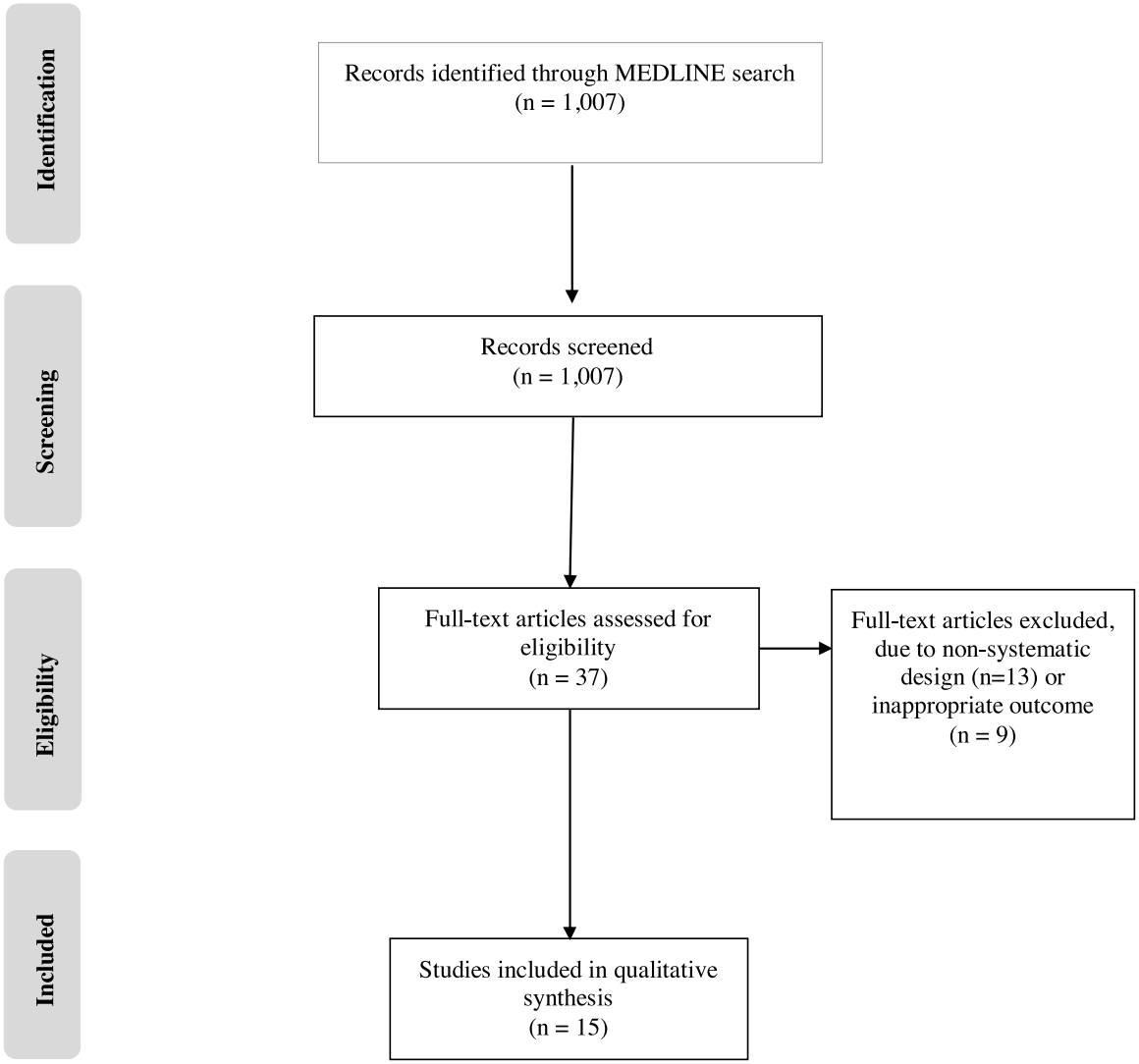


**Fig. 2.** Flowchart of included studies.

general population, the healthier cardiometabolic risk profile in women was attributed to estrogen, however, examining health changes in menopause in SCI women tend to focus more on subjective symptoms rather than CVD risk profile [14,38].

## 4. The landscape of sex and gender in SCI research

Men are around four times more likely to have SCI compared to women, but the epidemiology is slowly changing across the years, with a gradually increasing proportion of women with SCI. [39] Nevertheless, studies focusing exclusively on women remain sporadic and in studies in which women are included, they only comprise one-eighth up to a quarter of participants [1]. However, the ratio of males-to-females observed in the literature cannot be explained entirely by the SCI incidence. Some authors purposively excluded women from clinical studies to make the study participants more homogenous on confounding factors that may affect the outcome of interest.

Limited resources and small sample size in SCI research are truly a problem. We have noticed that in studies that enrolled both sexes, sex-specific analyses were often not performed due to small number of women included in analyses. Although sex-stratification often does not provide meaningful conclusions due to disparity in the number of males and females included, it can be used for other purposes. For example, providing sex-stratified analyses in original studies could be later used in meta-analyses. At the moment, the lack of such data precludes our ability to pool sex-specific effect estimates, further contributing to a large gap in evidence in women. Regardless of the cause of this gap in research evidence, the number of studies investigating cardiovascular function and risks in females with SCI is disturbingly low and warrants immediate action. [22]

## 5. Closing the knowledge gap

To close the evidence gap in SCI, it is crucial to conduct studies focused on female population, to investigate the disparities on risks and outcomes between sexes, to include a gender framework in the analysis, and to include female-specific variables (i.e., age at menarche, history of preeclampsia, menopausal status and age at menopause and menopausal hormone therapy use) in prospective observational studies and clinical trials for more inclusive research. Sex-specific disease risk assessment tools should also be adjusted to suit the population (i.e., modify the existing CVD risk prediction models or developed new SCI-specific models). Funding agencies and research institutions should implement regulations to ensure the inclusivity of all researches. Ethical committees should require research protocols to be gender-balanced. The International Spinal Cord Injury Data Set [40], the basic information collected on all patients with SCI, should include more gender-specific variables. To subvert the issue of low sample sizes, newer

**Table 1**
Characteristics of included systematic reviews.

| Lead author, publication year | Research questionaddressed in systematic review | Sex/gender reporting | | | |
|---|---|---|---|---|---|
| | | Male-only population | Male and female | Female-only population | Unknown sex |
| Carlson et al., 2009 [25] | To determine the effectiveness of exercise in improving carbohydrate and lipid metabolism in individuals with spinal cord injury (SCI). | 8/22 (36.37 %) | 0/22 (0 %) | 11/22 (50 %) | 2/22 (9.1 %) |
| Chilibeck et al., 2016 [18] | To determine the effectiveness of locomotor training in individuals with SCI on blood glucose control. | n.a. | n.a. | n.a. | 11/11 (100 %) |
| Cragg et al., 1999 [41] | To provide a comprehensive and up-to-date review of the clinical management of cardiovascular disease (CVD) and risk factors for individuals with SCI. | n.a. | n.a. | n.a. | 15/15 (100 %) |
| Da Silva et al, 2013 [19] | To explore the association between low-grade inflammation, SCI, and exercise to discuss a novel mechanism that might explain the beneficial effects of exercise involving an increase in catecholamines and cytokines in people with SCI. | n.a. | n.a. | n.a. | n.a. |
| Gibbs et al.,2017 [26] | To characterize rehabilitation interventions and summarize evidence on their efficacy/effectiveness to modify precursors to endocrine-metabolic disease risk in community-dwelling adults with chronic SCI. | 8/16 (50 %) | 0/16 (0 %) | 7/16 (43.75 %) | 1/16 (6.25 %) |
| Gilbert et al., 2014 [20] | To clarify the patterns of lipid profiles in SCI patients compared to able-bodied individuals as well as among subgroups of SCI patients stratified by sex, activity level, race, and level of injury. | 12/50 (24 %) | 13/50 (26 %) | 1/50 (2 %) | 24/50 (48 %) |
| Hicks et al., 2011 [16] | To determine the the effects of exercise on physical fitness in people with SCI. | n.a. | n.a. | n.a. | 82/82 (100 %) |
| Latifi et al., 2013 [23] | To investigate changes of leptin concentration in plasma in patients with SCI. | 5/5 (100 %) | 0/5 (0 %) | 0/5 (0 %) | 0/5 (0 %) |
| Neefkes-Zonneveld et al., 2015 [27] | TTTo explore the effect of long-term physical activity and acute exercise on markers of systemic inflammation in persons with chronic SCI. | 7/11 (63.64 %) | 3/11 (27.27 %) | 0/11 (0 %) | 1/11 (9.09 %) |
| Phillips et al., 2011 [28] | To explore the role of exercise as a therapy to alter arterial function in persons with SCI. | 5/27 (18.52 %) | O/25(0 %) | 1/27 (3.7 %) | 6/27 (22.22 %) |
| Saadeh et al., 2017 [15] | To review the evidence behind chanages in blood pressure in management after SCI. | n.a | n.a. | n.a. | 11/11 (100 %) |
| Shojaei et al., 2017 [29] | To review the evidence on management of obesity after SCI. | 9/25 (36 %) | 0/25 (0 %) | 1/25 (4 %) | 15/25 (6 %) |
| van der Scheer et al., 2017 [24] | To synthesize and appraise research testing the effects of exercise interventions on fitness, cardiometabolic health, and bone health among adults with spinal cord injury SCI. | 45 %–80 % | n.a. | n.a. | n.a. |
| West et al., 2012 [22] | To examine the effect of injury level on supine and seated cardiovascular function in individuals with SCI. | 48/98 (48.98 %) | 0/98 (0 %) | 30/98 (30.61 %) | 20/98 (20.41 %) |
| Wilt et al., 2008 [21] | To explore the role of carbohydrate and lipid disorders and relevant considerations in persons with SCI. | n.a. | n.a. | n.a. | 22/22 (100 %) |

n.a. indicates that information on sex/gender of study participants was not available.

epidemiological methods should be used to treat small sample sizes, and collaborative research (through international consortia and multi-centric studies) should be encouraged to generate epidemiologically sound data for women. Finally, researchers and clinicians gain a deeper understanding of how sex and gender affect the health outcomes in SCI.

## 6. Synthesis and conclusion

The proportion of women with SCI has been slowly increasing, and cumulatively, contribute to a significant health burden across time. Therefore, excluding women from observational and interventional studies to facilitate the research process and interpretation of findings creates a void in the clinical evidence for the rehabilitation of chronic SCI and short and long-term health risks in women with the injury. In particular, future studies shall explore in depth: (i) are the sex differences in CVDs and diabetes (as its major risk factor) reported in the general population also present in population with the SCI?, and (ii) how does menopause change the health risks of spinal cord injured women and are the risks similar to their able-bodied counterparts? The available evidence, though of limited methodological quality, is rooted in the male population and may not hold for females. Therefore, besides improving the overall quality of research in the SCI, inclusive research will ensure that everyone will benefit from the fruits of scientific advancements, regardless of sex and gender.

## Contributors

Peter Francis Raguindin contributed to drafting and revision of the manuscript.

Taulant Muka contributed to drafting and revision of the manuscript.

Marija Glisic was responsible for study concept and design, and contributed to drafting and revision of the manuscript.

## Conflict of interest

The authors declare that they have no conflict of interest.

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## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.maturitas.2021.03.00

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