

P23 - Quantifying sex bias in randomized clinical trials of major impact publications

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INTRODUCTION

This study aimed to examine sex bias in randomized clinical trials (RCT) published in main scientific journals.

METHODS

Three journals were chosen based on their 2021 impact factor (IF): New England Journal of Medicine, Lancet and Journal of the American Medical Association, including those specialized in areas in which sex differences had been documented previously (general/internal medicine, cardiac/cardiovascular systems, infectious diseases, and oncology). A PubMed search was performed to locate RCTs published in English during 2022. Sex-specific and paediatric studies were excluded. Information about first author's sex, absolute number of men and women enrolled, and diagnosis were collected. First author's sex was determined by name's inspection or with Internet searching, if ambiguous. All information was analysed by Microsoft Excel.

RESULTS

PubMed search resulted in 517 articles; a sample of 150 RCTs were selected by randomization. Twenty-nine were excluded and 121 articles were analysed. Globally, there were more men than women enrolled in RCTs (53% vs 47%). In 79% of the articles the first author was men. First women author did not include more women than men (49% vs 51%). When considering only phase III RCTs (53%), more women than men were enrolled (55% vs 45%). Regarding treatment areas, women were clearly underestimated in cardiac and cardiovascular systems (35% vs 65%) possibly due to the prevalence of these diseases.

CONCLUSIONS

In the selected sample of articles in high IF journals, women were represented in almost the same proportion as men, so the historical sex bias is being redressed.