

Gender Disparities in the Clinical Trial Enterprise: Lead Authorship in Gastroenterology Trials Registered on ClinicalTrials.gov, 2013-2019

Introduction

- Clinical trials are often the gold standard for evaluating the safety and efficacy of emerging evidence-based guidelines or new treatment modalities.
- However, there is growing concern regarding gender inequality at the authorship level.
- Women are still under-represented in leadership and authorship of these clinical trials.

Objective

- The aim of this study is to evaluate gender differences in lead authorship among gastroenterology clinical trials registered in the primary clinical trial database, ClinicalTrials.gov.

Methodology

- Records of interventional clinical trials registered on ClinicalTrials.gov between January 1, 2013 and December 31, 2019 were downloaded.
- A study set of only gastroenterology and hepatology trials was then created using disease condition terms (both Medical Subject Heading [MeSH] and non-MeSH) from the National Library of Medicine.
- The ClinicalTrials.gov identifier was extracted and a linked search was performed on PubMed for associated publications for each entry.
- From this subsequent study set, the first randomized controlled trial was evaluated for lead authorship gender and journal impact factor.

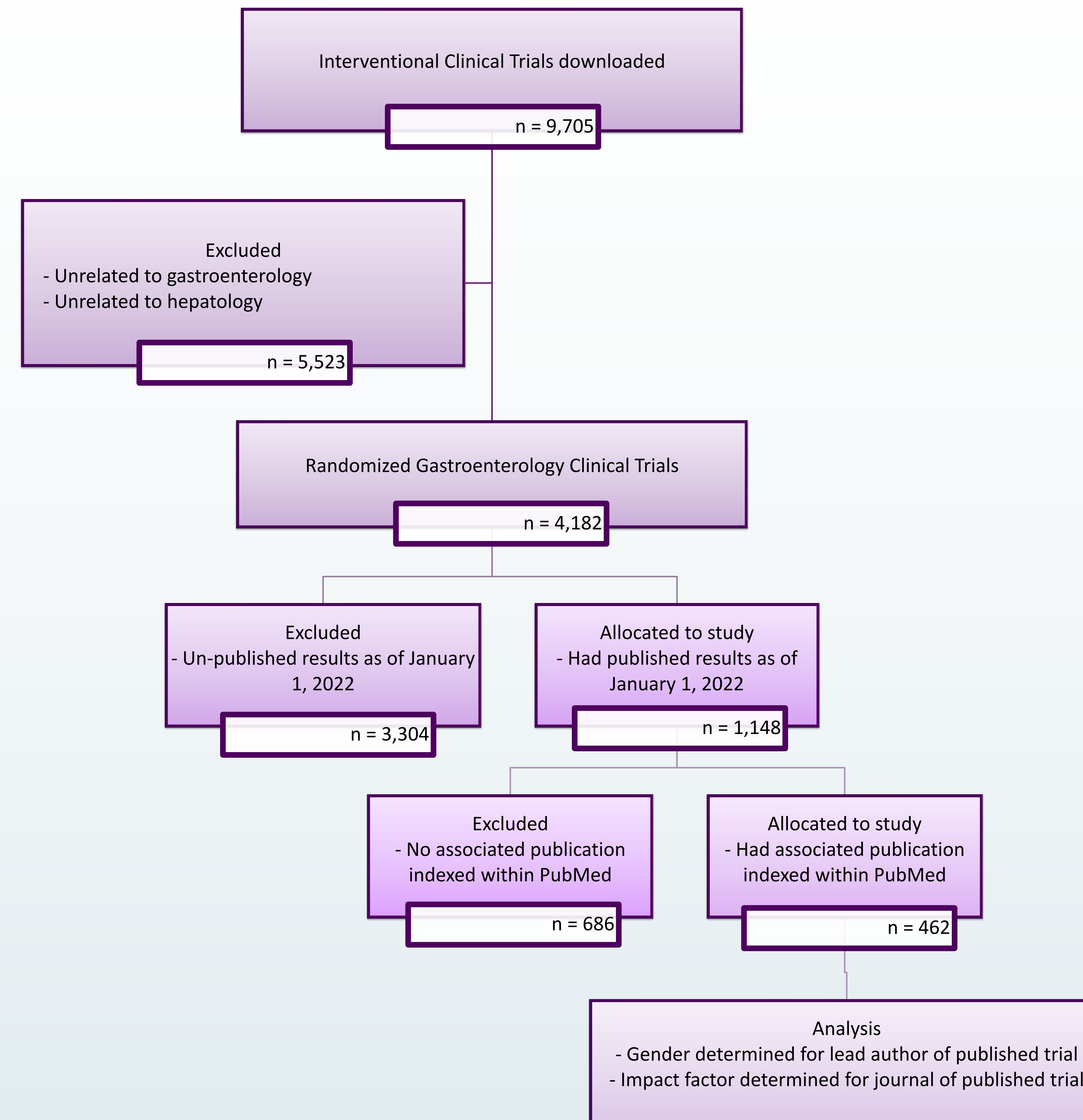


Table 1: Gender Disparities in Lead Authorship and Impact Factor in Gastroenterology Clinical Trials

	Male	Female
No. of lead authors of published trials	333	129
Average impact factor for journal of published trials	16.17	18.73

Results

- 9,705 trials were manually reviewed from which 4,182 were verified as trials relating to gastroenterology or hepatology.
- Of these, only 462 trials had results posted as of January 1, 2022 and an associated publication indexed within PubMed.
- The gender was determined for 100% of lead authors of published randomized controlled trials.
- The lead author was male in 333 (72.08%) trials and female in 129 (27.92%) trials.
- The mean impact factor for male first-authored publications was 16.17 ± 1.06 , while the mean for female first-authored publications was 18.73 ± 5.55 .

Conclusion

- Women are under-represented as leaders of gastroenterology clinical trials.
- According to this study, women represented less than 3 in 10 lead authors of gastroenterology trials in the examined time period.
- The rate of female first-authorship lags behind the broader rate of women entering the field.
- Recalibration efforts must address the structure and processes that lead to the gender gap in the clinical trial enterprise.
- Further assessment of barriers to women in authorship and leadership can increase diversity of future clinical trials, thereby improving general trial results.