

Gender Disparity in Clinical Trials for Trigeminal Neuralgia and Association with Outcomes



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INTRODUCTION

Trigeminal neuralgia (TN) is a chronic orofacial pain disorder. There has been a well documented predominance of female patients with TN compared to male counterparts.

Despite the disparity in prevalence, female patients often have higher levels of pain and have a longer duration of symptoms prior to being referred for treatment. The root cause of the gender disparities in care is poorly explored; however, unconscious bias and the representation of women in clinical trials may factor into this.

Additionally, animal models have suggested sex-based differences in response to medical treatments for TN, and clinical trials must account for these potential differences.

This project investigates patient representation, location of trials, and types of interventions in clinical trials for TN to better understand the evidence around differences that may contribute to gender disparity.

AIM

Clinical trials studying trigeminal neuralgia were collected from clinicaltrials.gov and the WHO International Clinical Trials Registry Platform.

Data were extracted from these studies. Gender disparity index (GDI) was calculated using the difference between the reported proportion of each gender and the reported proportion in prior publications.

Based on this, studies with female patients representing between 55% and 75% of the population were defined as having normal representation.

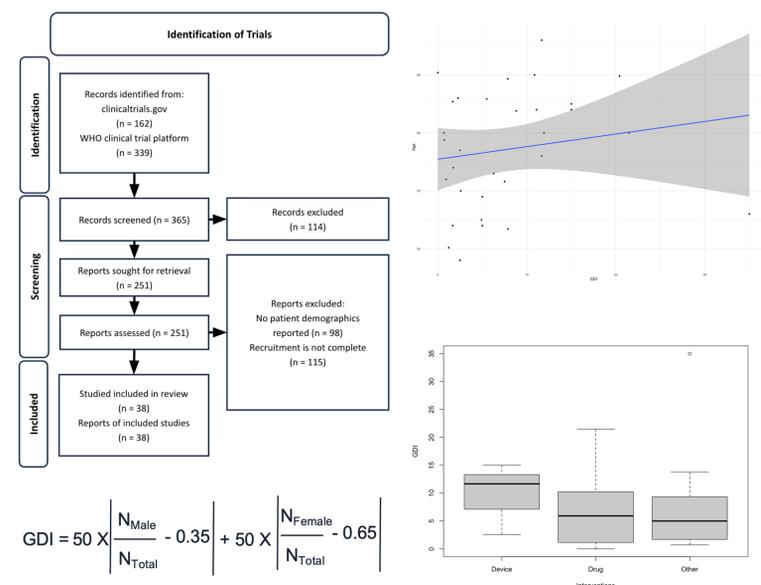
Studies outside of this range had a high GDI. Study details and conclusions were correlated to GDI using linear regression models.

RESULTS

38 trials reported gender demographics for their patient population. The articles were completed in 15 different countries with China publishing 11 trials followed by the United States who published 6.

There were 2,764 participants overall in the studies and 1,625 (58.5%) participants were female. Of these studies, 11 (28.9%) had a high GDI compared to the expected proportions.

The average age of the studies ranged from 49 to 68 years old, and studies with an older population were associated with higher rates of gender disparity (p-value =0.0361).



$$GDI = 50 \times \left| \frac{N_{\text{Male}}}{N_{\text{Total}}} - 0.35 \right| + 50 \times \left| \frac{N_{\text{Female}}}{N_{\text{Total}}} - 0.65 \right|$$

DISCUSSION

Notably, there was no correlation between gender disparity and duration of symptoms or baseline pain levels.

Although there is a well documented disparity between men and women for prevalence and treatment of TN, this analysis of published clinical trial data demonstrated minimal relationships between interventions and gender disparity.

However, there was still a substantial difference in gender representation for 28.9% of the trials.

CONCLUSIONS

Further research should explore the socioeconomic factors that contribute to this disparity and investigate potential efficacy differences between males and females for major TN treatments.