# Gender Disparity in Pituitary Adenoma Clinical Trials May Unintentionally Bias Results and Application to Clinical Scenarios

**Alexa R. Lauinger, Suguna Pappu, Ann Stroink**
Carle Illinois College of Medicine, Urbana, IL; Carle Bromenn Medical Center, Bloomington, IL

Carle Illinois
**COLLEGE OF MEDICINE**

**NASBS**
*North American Skull Base Society*

## INTRODUCTION

Demographic disparities in clinical trials can unintentionally bias the results of the trial or impact the target population. This is a historic problem that spans across specialties and disease types; however, it is more influential in diseases with a known variation of outcomes or prognosis based on gender or race. One such pathology is pituitary adenomas.

Pituitary adenomas in females are often smaller, have different gene expression, and are at a higher risk of recurrence. There may also be differences in risk of post-operative diabetes insipidus and hyponatremia.

For this reason, study cohorts should have similar representation in this disease to the population. In addition, prevalence of prolactinomas and corticotropic adenomas is higher in females, and clinical trials need to accurately represent this in their study cohort.

## AIM

The objective of this study is to investigate the diversity of clinical trials for pituitary adenoma treatments.

This information will help physicians apply the findings of these trials to their patient population

## METHODS

STUDY SELECTION

Using ClinicalTrials.gov, we queried studies related to pituitary adenomas, including functional and nonfunctional subtypes. Demographics and study characteristics were collected.

DISPARITY MEASURE

The racial disparity index (RDI) was calculated using United States census data in the formula:

$$RDI = ((Black_{study}/Black_{pop}) + (Other_{study}/Other_{pop}))/(White_{study}/Whitepop)$$

where pop refers to the expected number of participants based on the population.

Gender disparity was defined as having the percent of female study participants in the cohort less than 50%; while in the case of prolactinomas and corticotropic adenomas, that have a strong female predominance, gender disparity was defined as less than 80%.

## RESULTS

STUDY POPULATION

178 trials were originally queried; however, 8 were removed for including other pathologies, 74 had not completed recruiting, and 49 did not report gender or racial demographics. After screening, 47 trials were included to look at gender disparity and 18 were included to look at racial disparity.

RELATIONSHIP WITH GENDER DISPARITY

25 of 47 trials (53.2%) of trials demonstrated gender disparity, which was more common in studies exploring a drug type intervention (p-value = 0.03). However, adenoma subtype, funding source, and country were not significantly associated with gender disparity. 4 of 18 trials (22.2%) of US based trials showed racial disparity. However, there were not any significant study characteristics that correlated with this.

DISCUSSION

Gender disparity was correlated to the type of intervention, which may be a result of females having a higher prevalence of functional adenomas that require surgical removal. However, this unbalanced cohort may still impact patient and physician decision-making in clinical settings. The results of this study are likely limited by the small sample size, especially in trials that reported racial demographics.

## CONCLUSIONS

Our findings demonstrate that there are still a large percent of clinical trials studying pituitary adenomas that demonstrate gender or racial disparity in their study cohort compared to the general population.

It demonstrates a need for increased awareness of study cohorts in clinical trials, especially for diseases that have a strong predominance for gender or race.

These studies should appropriately represent the population or limit the study results to apply to a narrower demographic to ensure accurate application to clinic scenarios.

Further research is needed to explore how the outcomes of these studies may be associated with disparities in their study cohorts.

Carle
UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN