

The File Drawer Effect in Gastroenterology and Hepatology Literature

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Introduction

Reviewing the published literature is an important part of a physician's job in the process of making clinical decisions, creating guidelines, and considering future research endeavors. It is the cornerstone of evidence-based decision making.

Biases in the published literature can affect all of these aspects of modern medicine. The File Drawer Effect, or the tendency for studies with statistically significant results to be published and those with unequivocal or negative findings to remain unpublished or less known, can have a significant impact on the scientific literature available in a field.¹

Underreported negative findings may negatively impact scientific understanding in several ways; including, but not limited to:

- Incomplete understanding of the evidence base for medical decision-making;
- Wasted resources and effort due to redundant studies; and
- Ethical considerations for participants assured their study participation will impact the scientific knowledge base.²⁻⁴

The File Drawer Effect has been studied for decades, but to the extent of our understanding this study is the first to attempt to quantify the impact of this concept in gastroenterology and hepatology literature.

Purpose

To further assess the impact of the File Drawer Effect in the field of Gastroenterology, we sought to examine the proportion of studies with statistically significant results published in the gastroenterology and hepatology literature compared to the proportion of published studies with unequivocal or negative results.

Methods and Materials

We reviewed all original articles published in 2012 and 2017 in four national gastroenterology and hepatology journals (*Gut*, *Journal of Crohn's and Colitis*, *Hepatology*, and *Clinical Gastroenterology and Hepatology*). Case reports, editorials, and literature reviews were excluded from the study.

Our primary study outcome was the proportion of studies with a positive finding. Findings were considered positive if the study included statistically significant results.

The number of times the study was cited according to Google Scholar and the type of study (clinical or basic) was also recorded.

Results

In total, 1,414 articles were reviewed. Three (3) studies were excluded from the analysis due to study results that could not be defined as positive or negative.

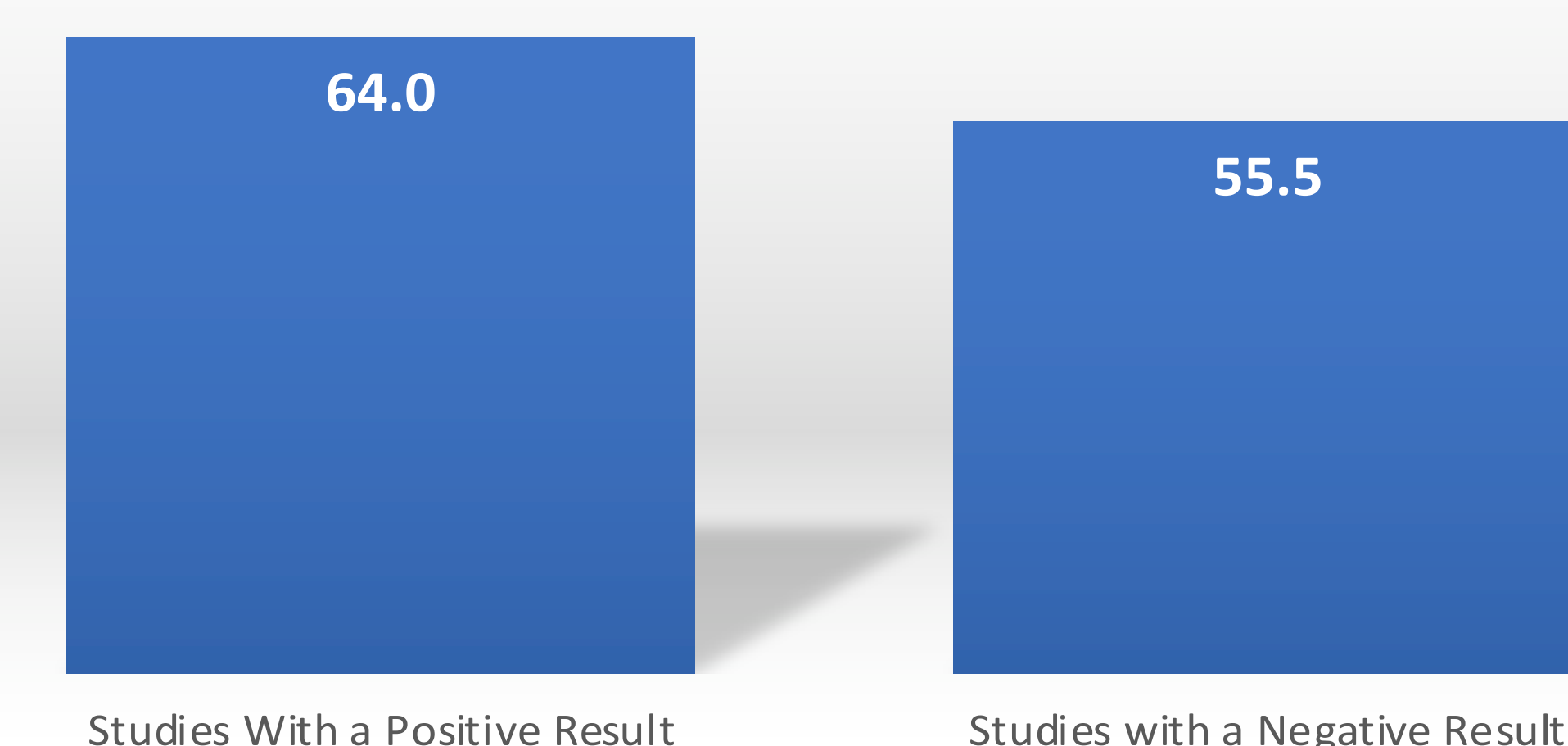
Of the studies included, 97.31% (1,373) had at least one positive study result and 2.69% (38) had all negative study results.

The proportion of articles with positive findings in 2012 (96.9%) was lower, though not significantly, from the proportion of articles with positive findings in 2017 (97.8%) ($p=0.38$).

The proportion of basic science articles with positive findings (99.3%) was significantly greater than the proportion of clinical research articles with positive findings (95.9%) ($p<0.01$).

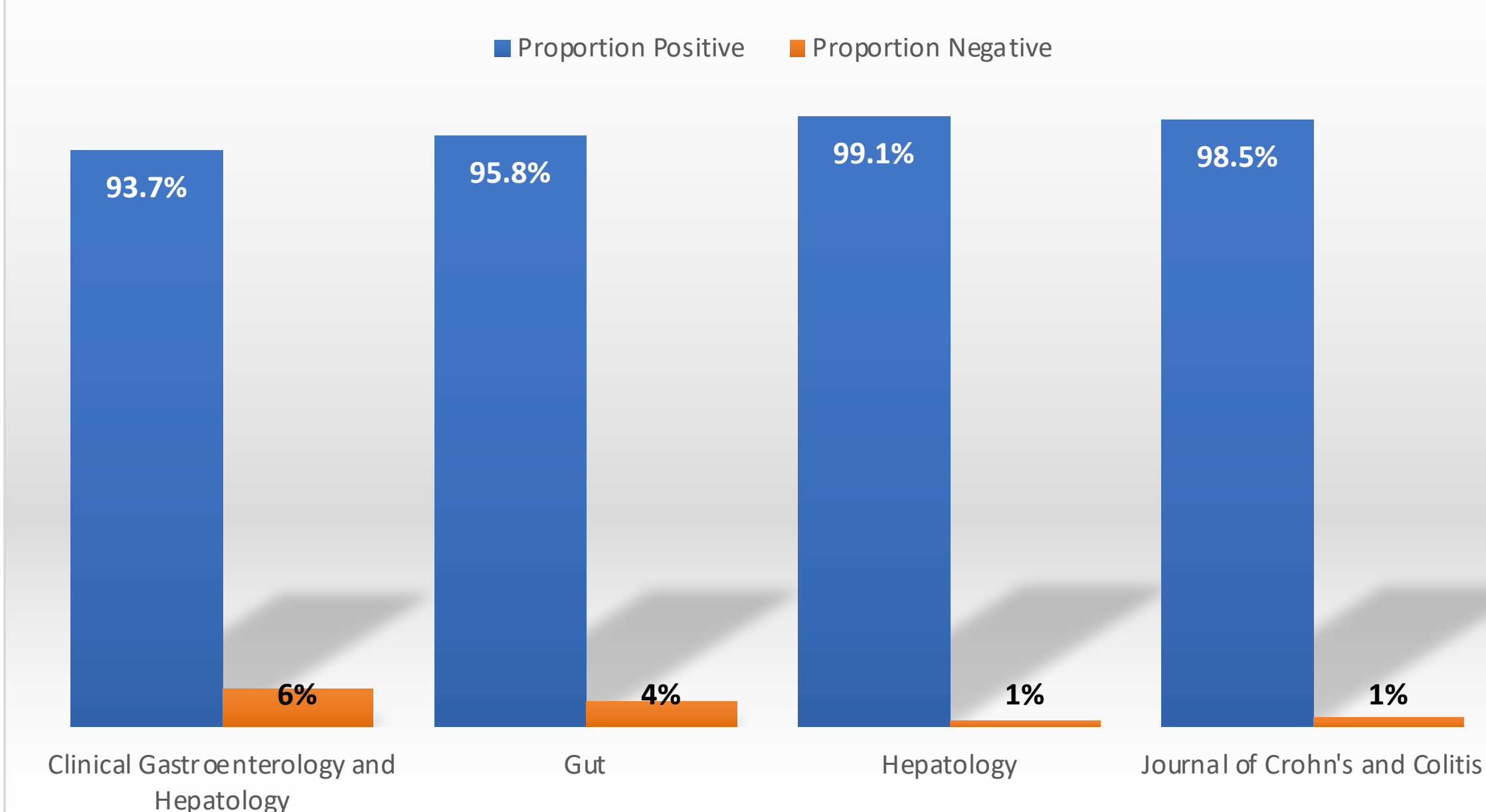
The median number of times a study was cited was higher for studies with a positive result (64.0) than for studies with a negative result (55.5); however, this difference was not found to be statistically significant by Mann Whitney U test ($p=0.24$).

Figure 1. Difference in the Median Number of Citations for Studies with Positive vs. Negative Results



The proportion of published studies with a positive result differed significantly across journals as indicated by chi-squared testing ($p<0.01$). The highest proportion of studies with positive findings was seen in *Hepatology* (99.1%). *The Journal of Crohn's and Colitis* also saw a fairly high proportion of studies with positive findings (98.5%). *Clinical Gastroenterology and Hepatology* and *Gut* included lower than expected proportions of studies with positive findings at 93.7% and 95.8%, respectively.

Figure 2. Proportion of Published Studies with Positive vs. Negative Results By Journal



Discussion

An overwhelming majority of studies published in the selected journals were found to be positive, and this proportion increased slightly between 2012 and 2017. While a study's impact did not significantly differ between those with statistically significant and insignificant results, this could not be adequately examined due to the low sample size of negative studies (only 38) and subsequent lack of statistical power. The low representation of studies without statistically significant results, especially in basic research, highlights a possible publication bias that is prevalent across the specialty's literature. This bias can potentially drive poor clinical practice, and steps should be considered to further study this effect.

Strengths of this study include the large overall sample size and comprehensive data collection including all studies published in the four mentioned national gastroenterology and hepatology journals in 2012 and 2017.

Limitations include small sample sizes in certain sub-analyses, lack of continuous data from years between 2012 and 2017, and the descriptive nature of the study with the potential for a small degree of subjectivity in classifying study results as positive or negative. Additionally, the selected journals do not encompass all published papers related to gastroenterology and hepatology during our study time frame and data collected included only published data.

Conclusions

A predominance of studies published in the selected journals in 2012 and 2017 reported significant findings, which supports concern that the File Drawer Effect may contribute to bias in gastroenterology and hepatology literature. Further research should incorporate a greater sample size across consecutive years to yield improved statistical power and evaluate trends over time.

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