CLINICAL VS. STATISTICAL RELEVANCE IN VENTRAL HERNIA REPAIR LITERATURE: A CALL FOR CLEARER DISTINCTIONS

Diego L Lima, MD, MSc[1]; Carlos Andre B Silveira, MD[2]; Ana Caroline D Rasador, MD[2]; Raquel Nogueira, MD[1]; Shan Lansing, MD[3]; Vahagn Nikolian, MD[3]; Scott Melvin, MD[1]; Leandro T Cavazzola, MD, PhD[4]; [1]Montefiore Medical Center; [2]Dignity Health St. Joseph's Hospital; [3]Oregon Health and Science University; [4]Federal University of Rio Grande do Sul

Introduction

- In ventral hernia repair (VHR) research, statistically significant findings are often emphasized without proper consideration of clinical relevance
- This can lead to misinterpretation of data and affect clinical decision-making.
- Our study aimed to assess the frequency with which clinical relevance is reported and distinguished from statistical significance in comparative studies of VHR.

Methods

- A comprehensive search was conducted across seven Surgery Journals with impact factor higher than 2, for articles comparing techniques in VHR.
- Studies published since 2018 were included, and non-clinical outcomes, such as cost-effectiveness, were excluded.
- Two independent reviewers screened the articles, identifying whether a clinical relevance cutoff was defined, if clinical relevance was addressed, and whether conclusions were based solely on statistical significance.

STUDIES SELECTION

- Hernia
- Surgical Endoscopy
- Annals of Surgery
- Surgery
- World Journal of Surgery
- JAMA Surgery

52
Studies were identified as VHR Studies

43
Studies presented

- *6 RCTs*
- *37 cohort studies*

MAIN FINDINGS

There is a critical gap in the reporting of clinical relevance in VHR studies.

Statistically Significant Findings

- Only 2 studies (4.7%), both RCTs, defined a clinical relevance cutoff for their outcomes
- Six studies (14%) addressed the concept of clinical relevance, with 5 noting that their findings might not hold clinical importance.
- 1 study highlighted the importance of weighing risk-benefit factors in clinical practice when considering statistically significant outcomes.
- 3 cohort studies concluded the superiority of a surgical technique despite lacking statistical and clinical relevance.
- 7 studies, including 2 RCTs, did not make conclusions of superiority despite presenting statistically significant results.

Conclusion

- The findings reveal a critical gap in the reporting of clinical relevance in VHR studies.
- Even in RCTs the distinction between statistical significance and clinical importance is often neglected.
- There is a pressing need for future studies to define clinical relevance thresholds and to better contextualize their findings in relation to patient-centered outcomes.

Montefiore
HEALTH SYSTEM