When Numbers Lie: The Disconnect Between Statistical Significance and Clinical Relevance in Inguinal Hernia Pain intensity Studies

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Introduction

Statistical Significance in Clinical Studies

Many studies define their findings as statistically significant when the p-value is less than 0.05.

Pain Intensity Measurement in Hernia Surgery

Pain intensity is a crucial patient-reported outcome in hernia surgery, commonly measured using the Visual Analogue Scale (VAS).

Clinical Relevance of Statistical Differences

•Recent research suggests that a difference of less than 1 point on the VAS with a $p<0.05$, despite statistical significance, may not be clinically relevant.

Methods

- We searched the **most relevant surgical jour**nals for comparative articles analyzing **Inguinal Hernia Repair**, published since 2018.
- Studies included in the search used the **VAS pain scale** to assess **pain intensity in hernia surgery**.
- Two authors independently screened articles for **definitions of clinical relevance**, **statistical significance**, and whether they suggested superiority of an intervention or control based on the p-value, despite a VAS difference of less than 1 point.

STUDIES SELECTION

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

169
Studies were identified as IHR Studies

45
Studies presented VAS pain analysis

- *15 studies of surgical techniques (33.3%)*
- *19 surgical materials (42.2%)*
- *21 RCTs (46.7%)*
- *15 cohort studies (33%)*
- *9 meta-analyses (20%)*

MAIN FINDINGS

None of the studies included a cutoff for the VAS clinical relevance.

Statistically Significant Findings

- 25 (55.6%) studies = Statistically significant difference.
- Among the 25 statistically significant studies, 11 (44%) showed a VAS difference of 1 point or more.
- 14 studies presented no clinically relevant VAS difference:
  - 12 (85.7%) supported a difference in pain intensity based solely on the p-value.
  - 2 (14.3%) acknowledged their results may not be clinically relevant (both meta-analyses).

Randomized Controlled Trials (RCTs)

- 9 (42.9%) RCTs showed statistical significance.
- Only 2 (22.2%) of these RCTs had a VAS difference greater than 1 point.
- None of the remaining 7 RCTs discussed that their statistically significant results may not be clinically relevant.

Conclusion

1. Statistical Significance vs. Clinical Relevance

• Statistical significance, based on a p-value of less than 0.05, does not always correlate with clinical relevance.

• Our findings revealed that the widely recommended clinical relevance cutoff of a 1-point difference on the VAS tool is often overlooked in inguinal hernia clinical studies. Authors frequently focus on statistical significance, even when their results lack meaningful clinical relevance.

2. Studies Design

• Randomized controlled trials (RCTs) were more likely to show statistical significance but failed to demonstrate a clinically relevant VAS difference, highlighting the need for a better understanding of clinical significance in pain intensity measurement.

• Meta-analyses are more likely to acknowledge the lack of clinical relevance, underscoring the importance of considering both statistical and clinical significance in pain studies.

3. Need for Clearer Guidelines on Clinical Relevance

•There is a lack of consensus on the definition of clinical relevance for the VAS pain scale and future studies should establish clearer clinical relevance cutoffs for pain intensity outcomes to ensure that statistically significant differences translate to meaningful patient outcomes.

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