



What is the minimal clinically important difference, and why does it matter?

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PRACTICAL SCENARIO

In a hypothetical randomized controlled clinical trial, researchers compared the effect of bronchodilator A vs. bronchodilator B on FEV₁ in patients with COPD. Although the results showed that A was superior to B in improving FEV₁ and that this difference was statistically significant, did this change in FEV₁ result in fewer symptoms, or did it increase the participants' self-perceived ability to perform activities of daily living?

To answer these and other clinical outcome-related questions, it is crucial to understand the concept of the minimal clinically important difference (MCID).

DEFINING THE MCID

One of the many challenges of translating scientific evidence into clinical practice is the interpretation of data in light of clinical meaningfulness. We commonly find reports of statistical results, such as p-values, confidence intervals, and effect sizes. The MCID conveys results that are meaningful to patients. Depending on what outcome we are measuring, this change may be self-reported or objectively measured.

The MCID refers to the smallest change in an outcome that represents a meaningful change for the patient.^(1,2) There are different methods to determine the MCID, but the major points are that the change has to be greater than the measurement error of the instrument that we are using to assess the outcome and it has to be large enough for patients to perceive the clinical change.

MCID IN RESEARCH AND CLINICAL SETTINGS

When designing studies that compare the effects of interventions, researchers should consider including thresholds for the MCID together with statistical significance.⁽²⁾

The MCID for a given test can be determined using expert consensus, using patient assessments anchoring the change to a subjective perception of change, or using statistical methods, which generally need validation. Interestingly, the same instrument may have different MCID thresholds according to specific study populations. For example, the six-minute walk test has different MCID

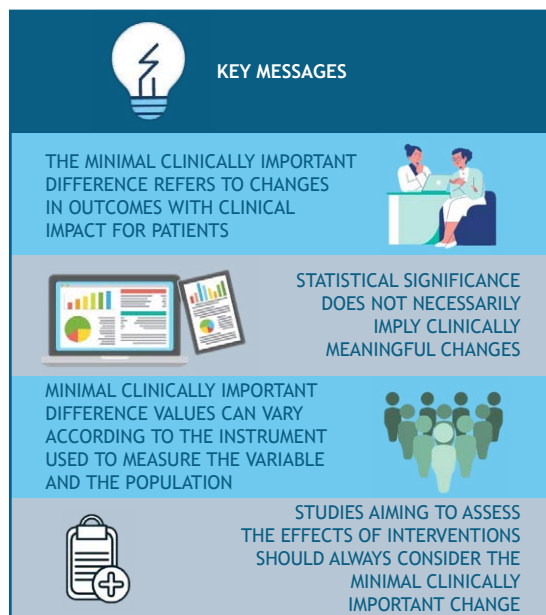


Figure 1. Key messages.

for patients with COPD, patients with heart failure, and apparently healthy adults.

In the hypothetical trial of our practical scenario, the investigators found that the variation in FEV₁ was 241 ± 38 mL in the bronchodilator A group and 91 ± 14 mL in the bronchodilator B group. Considering that the MCID for FEV₁ in patients with COPD is 100 mL, we can conclude that bronchodilator A is statistically superior to bronchodilator B and that the change in FEV₁ is clinically meaningful.

CONCLUSION

Using patient-centered outcomes and aligning clinically relevant effects with statistical significance are important steps in the process of translating scientific clinical knowledge into evidence-based practice. Understanding the concept of the MCID is crucial to analyze and interpret the results of clinical interventions. In both research and clinical settings, we should consider MCIDs when analyzing and interpreting clinical outcome results (Figure 1).

REFERENCES

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