Statistical Fragility of Studies Comparing Revision Rates after Manual Versus Robotic-Assisted or Computer-Assisted Total Hip Arthroplasty - A Systematic Review of Randomized Controlled Trials

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INTRODUCTION: Despite the growing use of computer-navigated and robotic-assisted total hip arthroplasty (THA), uncertainty remains regarding their long-term outcomes compared to manual THA. Therefore, we used the concept of Reverse Fragility Index (RFI) to assess the statistical robustness of available randomized controlled trials (RCTs) in literature.

METHODS:

RCTs reporting revision rates for manual and robotic-assisted/computer-navigated THA were included in our systematic review. Our search included all RCTs published until 4/4/2024. The RFI, defined as the minimum number of event reversals necessary to change a nonsignificant result to statistically significant, was calculated for each study using a threshold of p<0.05. The Reverse Fragility Quotient (RFQ), which adjusts the RFI relative to the study sample, was additionally calculated.

RESULTS: Nine clinical trials with 894 patients were analyzed. The median RFI was 5 (IQR, 4 to 5) for both computernavigated and robotic-assisted THA subgroups, meaning that a median of 5 events would be needed to change the results from nonsignificant to significant. The median RFQ was 0.045 (IQR, 0.036 to 0.083), indicating that an event reversal in 4.5% of patients would be sufficient to make the results become significant. The median number of patients lost to follow-up was 6 (IQR, 0 to 41). Of nine studies, seven (78%) had loss to follow-up greater than or equal to its RFI, indicating high fragility. Additionally, over half of the studies showed a relatively higher fragility in the manual THA group compared to the computer-navigated and robotic-assisted THA subgroups.

DISCUSSION AND CONCLUSION:

To our knowledge, our study is the first to determine the RFI in RCTs that compare manual to computer-navigated or robotic-assisted THA. We observed significant statistical fragility in all analyzed RCTs. Notably, over 75% of the studies reported a loss to follow-up exceeding the RFI, further highlighting the high fragility of the results. We recommend routine reporting of RFI and RFQ metrics in future RCTs with nonsignificant findings and careful interpretation of P-values.

