The Quality of Randomized Controlled Trials in Hand, Wrist and Elbow Surgery: A Critical Analysis of Current Literature

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BACKGROUND

- High quality research is increasingly emphasized as hand surgeons strive to practice evidence-based medicine.
- Randomized controlled trials (RCTs) yield Level I evidence.
- A high level of evidence is not necessarily synonymous with high quality research.
- Previous work has found concerns with surgical RCTs.

PURPOSE

To evaluate the quality of hand, wrist, and elbow RCTs.

MATERIALS AND METHODS

- RCTs from top 6 Orthopedic Journals (by impact factor)
- Two reviewers were blinded and randomly assigned
- Quality of study assessed by the Modified Coleman Methodology (MCM) score and JADAD scale
- Quality of reporting assessed using the Consolidated Standard for Reporting Trials (CONSORT) checklist.
- Primary outcome: Modified Coleman Methodology Score

RESULTS

Average MCM score was 54.9 out of 100

<table>
<thead>
<tr>
<th>Categorical Score</th>
<th>Number of Studies</th>
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<tbody>
<tr>
<td>Excellent (85-100)</td>
<td>0</td>
</tr>
<tr>
<td>Good (70-84)</td>
<td>10</td>
</tr>
<tr>
<td>Fair (55-69)</td>
<td>22</td>
</tr>
<tr>
<td>Poor (0-54)</td>
<td>31</td>
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</tbody>
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Table 1. Categorical distribution of RCTs according to MCM score.

Good and poor studies differed significantly (p<0.05) in terms of:
- Enrollment Rate
- Power Analysis
- Withdrawal and drop-out description
- Blinding
- Outcome assessment using valid instrument and independent assessor
- Randomization method, type, and implementation

CONCLUSION

- Many hand, wrist, and elbow RCTs are of suboptimal quality.
- Despite their high level of evidence, RCTs should be critically assessed.
- Common methodological deficiencies may impact the validity of results and conclusions drawn from RCTs.

REFERENCES


