A Critical Review of The MINT Trials

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Outline

1. Patient Selection
2. Procedure Technique
3. Control Intervention
4. Data Analysis
5. Interpretation of Results
Figure 1. Flow of Patients Through Enrollment in the 3 Randomized Clinical Trials

10592 Potential participants

- 5168 Included in observational study

5424 Patients asked to participate in 1 of 3 trials based on suspected source of pain

2133 Asked to participate in the facet joint trial

- 1882 Excluded
  - 1202 Declined participation
  - 258 Negative diagnostic facet joint block
  - 277 Psychological problems
  - 52 BMI > 35
  - 93 Aged > 70 y

2498 Asked to participate in the sacroiliac trial

- 2770 Excluded
  - 1666 Declined participation
  - 202 Negative diagnostic sacroiliac joint block
  - 257 Psychological problems
  - 47 BMI > 35
  - 83 Aged > 70 y
  - 15 Other

793 Asked to participate in the combination trial

- 591 Excluded
  - 298 Psychological problems
  - 52 BMI > 35
  - 102 Aged > 70 y
  - 139 Other

251 Randomized
See Figure 2

228 Randomized
See Figure 2

202 Randomized
See Figure 3

BMI indicates body mass index (calculated as weight in kilograms divided by height in meters squared).

a Observational study was performed alongside randomized clinical trials; results from the observational study are not reported in this article.

b Participants not eligible for participation due to 1 positive exclusion criterion or more could be included in the observational study.

c Participants were excluded based on psychological problems, assessed by validated questionnaires.
Lumbosacral Zygapophyseal “Facet” Joint
SIS Guidelines: Diagnosis of Facet joint pain

- Dual, comparative blocks
- 0.5mL local anesthetic
- Contrast
Schwarzer et al. 1994

• Single diagnostic MBN block (>50% relief)
• 38% false positive rate*

• *Second, comparative MBN block (>50% relief) used as the criterion standard for “true” facet joint-mediated pain.
Appropriate conventional lumbar MBN neurotomy technique

Correct

Dreyfuss et al. 2000

- Dual MBBs (>80% relief)
- 60% of subjects:
  - >80% relief at 1 year
- 87% of subjects:
  - >60% relief at 1 year
- Technical success of 90.5% evidenced by multifidi EMG

MacVicar et al. 2013

- Dual MBBs (100% relief)
- 58% of subjects:
  - complete pain relief >6 months
  - complete restoration of ADLs, no further medical care, return to work
- Median duration of complete relief: 15 months
- Median duration of complete relief for repeat: 13 months.
Mint Trial Diagnostic Criteria for Facet Joint Pain

• Single MBN blocks
• >50% relief

*High* false positive rate
Mint Trial Denervation Techniques for Facet Joint Pain
Sacroiliac Joint/ Dorsal Ligament Complex
Appropriate diagnosis of SIJ/Dorsal ligament pain?

- Intra-articular injection?
- Sacral Lateral Branch blocks?
Dreyfuss et al. 2009

Cohen et al. 2008

- Double-blinded RCT (n=28), RF vs. Sham
- >75% relief with single SIJ anesthetic injection
- Success: >50% pain reduction AND >10 pt ODI impr. OR >20% reduction in opioid use
- **Significantly greater success rate in active RF group**

![Graph showing percentage of patients with positive outcomes at 1, 3, and 6 months post procedure for Sham and Cooled-RF groups.](image)

Mint Trial Diagnostic Criteria for SIJ/Dorsal Ligament Pain

- Single site, single depth lateral branch blocks
- Levels?
- >50% relief

Selection protocol *not* validated
Mint Trial Denervation Techniques for SIJ/Dorsal Ligament Pain

• Cooled RFN with epsilon
• Palisade technique with conventional technology
• Multielectrode probe (Simplicity III)

*Not* equivalent treatments

Intervertebral Disc
Mint Trial Diagnostic Protocol for Discogenic Pain

• Discogenic Pain Trial: terminated
• Combination Pain Trial:
  • Allocation based on history and physical examination findings alone
  • IASP/SIS operational criteria used for provocation discography?
Mint Trial Denervation Techniques for Discogenic Pain

- Biacuplasty
- Intradiscal electrothermal therapy

Some beneficial effects in a carefully selected patient population

Require much more stringent diagnostic criteria

Control Intervention

• Control treatment (PT or an exercise program) already received prior to enrollment in the study?
• Nature and “dose” of PT/exercise received in all study groups?
Data Analysis
Group Mean Data

- RFN group’s mean pain reduction @ 3 months reached MCIC (NRS >2) in all three trials
- MCIC was not reached in any of the exercise-only groups

<table>
<thead>
<tr>
<th>MINT Trial Arm</th>
<th>Mean NRS reduction RFN+exercise vs. exercise</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facetogenic Pain</td>
<td>-2.1 vs. -1.7</td>
<td>(p&lt;0.05)</td>
</tr>
<tr>
<td>SIJ-mediated Pain</td>
<td>-2.4 vs. -1.6</td>
<td>(p=0.03)</td>
</tr>
<tr>
<td>Combination Pain</td>
<td>-2.4 vs. -1.5</td>
<td>(p=0.01)</td>
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Categorical analysis of global perceived recovery @ 3 months, corrected for worst-case scenario analysis.

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<th>MINT Trial Arm</th>
<th>Responders by GPR RFN+exercise vs. exercise</th>
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<tr>
<td>Facetogenic Pain</td>
<td>34% (95% CI 26-43%) vs. 21% (15-29%)</td>
<td>p=0.02</td>
</tr>
<tr>
<td>SIJ-mediated Pain</td>
<td>37% (95% CI 28-47%) vs. 17% (11-25%)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>Combination Pain</td>
<td>29% (95% CI 21-39%) vs. 13% (7-21%)</td>
<td>p&lt;0.01</td>
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</tbody>
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Summary

• Stringent Diagnostic Criteria are vital for accurate diagnosis

• RFN techniques are *not* all equivalent – anatomy must be considered!

• Appropriate use/interpretation of MCIC and categorical outcome data

• Maintain a critical eye – large RCTs are *not* inherently flawless studies
Review Article

Guidelines for Composing and Assessing a Paper on the Treatment of Pain: A Practical Application of Evidence-Based Medicine Principles to the Mint Randomized Clinical Trials

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