Reporting and Interpreting quality of life data

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Presentation Outline

✓ “Oral Health-Related Quality of Life” ("OHRQoL")
  ✓ Definition / concepts
  ✓ State of play: measures
  ✓ Challenges in measurement - problems in interpretation: aggregate scores

✓ Interpretability
  ✓ Different approaches
  ✓ Minimally Important Difference (MID)
  ✓ Reporting and interpretation guide
Subjective measures of oral health

1. Single standing questions.
   - Self-Rated Oral Health
   - Perceived Dental Treatment Needs

2. Battery of questions
   - Pain and its effects daily life (even for young children)
   - Dental Discomfort Questionnaire
   - Chewing Ability (usually for older adults)

3. Oral Health-Related Quality of Life (OHRQoL) indicators
   - Composite measures - different domains / age groups
Quality of Life - definitions

- Quality of Life is defined as “individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” ¹

- Quality of life measures: “extent that health status and conditions disrupt normal social-role functioning and bring about major changes in behaviour” ²

OHRQoL indices are complementary to clinical measures

Conceptual Model for oral health

Disease → Impairment → Functional Limitation → Disability → Handicap

Discomfort → Death

Outcome Measures Model

“OHRQoL” indicators: state of play

✓ “OHRQoL” measures for adults
  ✓ OHIP-14 1
  ✓ OIDP 2
  ✓ GOHAI 3
  ✓ OHQoL-UK 4

✓ And few “OHRQoL” measures for children
  ✓ CPQ11-14 5
  ✓ Child-OIDP 6
  ✓ ECOHIS 7

“OHRQoL” measures: Context / applications

✓ Epidemiological studies - profile of functional, psychological and social impacts of oral conditions

✓ Studies assessing the relationship between clinical and subjective domains

✓ Clinical trials - effectiveness of interventions (“OHRQoL” as an outcome measure)

✓ Studies for the assessment of treatment need, in combination with clinical measures
What do “OHRQoL” scores measure?

✓ Frequency / (severity) of oral impacts
✓ Meaningless “OHRQoL” aggregate scores
  ✓ What does a score of 6 in the OHIP-14 scale mean?
  ✓ What profile does a score of 5 in the OIDP scale correspond to?

➢ Clinical relevance of scores?
✓ “Reporting aggregate scores and assessing the statistical significance of differences is insufficient in and of itself” ¹

Challenges with “OHRQoL” scores

✓ Different sets of responses (profile) – same score
  • OIDP score of 12: frequency=3 and severity=1 for 4 daily life activities (eating, speaking, smiling, social contact)
  • OIDP score of 12: frequency=3 and severity=4 for difficulty eating
  • OHIP-14 score of 12: “hardly ever” (1) to 12 items
  • OHIP-14 score of 12: “very often” (4) to 3 items

✓ Way out? Alternative scoring formats
  ✓ Prevalence
  ✓ Extent
  ✓ Severity / intensity
Meaningless “OHRQoL” means?

✓ P values are not sufficient: size of differences?
✓ Mean change scores are “complex and controversial” ¹
✓ Change can occur in both directions - mean change scores just give average change
✓ Same mean change score - different change profiles
✓ Is the difference (change) meaningful?

➢ “Differences or changes in scores... give the direction of difference, without any notion of scale or (more importantly) intrinsic meaning” ²

Interpretability of aggregate scores

- **Interpretability**: “the degree to which one can assign qualitative meaning— that is, clinical or commonly understood connotations— to quantitative scores”

- Are changes *clinically significant or meaningful* to the person?

- Both cross-sectional and longitudinal studies

- **Minimally important difference (MID)**: “smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side-effects and excessive cost, a change in patient’s management”

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Assessing the MID: approaches / methods

- **Distribution-based (internally referenced)**
  1. Effect size
  2. Standardised Response Mean
  3. Standard Error of Measurement
  4. Norman’s rule of thumb

- **Anchor-based (externally referenced)**
  1. Known clinical groups
  2. Population norms
  3. Global transition ratings
Distribution-based methods

1. Effect size (ES)
   \[ ES = \frac{\text{mean change score}}{\text{sd baseline score}} \]

2. Standardised Response Mean (SRM)
   \[ SRM = \frac{\text{mean change score}}{\text{sd change score}} \]

3. Standard Error of Measurement (SEM)
   \[ SEM = \text{sd baseline score} \times \sqrt{1-\alpha} \]

4. Norman’s rule of thumb
   \[ \text{MID} \sim \frac{1}{2} \text{sd baseline score} \]
OHIP-14 scores by socioeconomic and clinical status: Canadian adults

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>P</th>
<th>ES</th>
<th>SEM</th>
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<tr>
<td><strong>Education</strong></td>
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<tr>
<td>Secondary</td>
<td>20.1</td>
<td>&lt;0.001</td>
<td>0.24</td>
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<tr>
<td>Higher</td>
<td>18.3</td>
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<tr>
<td><strong>Income</strong></td>
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<tr>
<td>Lowest</td>
<td>17.2</td>
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<td>0.78</td>
<td>2.7</td>
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<tr>
<td>Highest</td>
<td>23.0</td>
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<tr>
<td><strong>Oral health</strong></td>
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<tr>
<td>Dentate</td>
<td>18.6</td>
<td>&lt;0.001</td>
<td>0.42</td>
<td>2.7</td>
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<tr>
<td>Edentate</td>
<td>21.8</td>
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Anchor-based methods

1. Known Clinical groups / benchmarks
   (e.g. dentate vs edentate: consensus?)

2. Population norms
   (large epidemiological surveys – EQ-5D)

3. Subjective global transition ratings of oral health or quality of life
   (subjects reporting “minimal important change” or difference between adjacent categories)
OIDP among periodontal patients (n=45): score over time and MID

<table>
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<tr>
<th></th>
<th>Generic OIDP</th>
<th>Perio-Specific OIDP</th>
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<tr>
<td>Mean score at baseline (SD)</td>
<td>7.7 (8.4)</td>
<td>6.9 (7.3)</td>
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<tr>
<td>Mean score at 1 month (SD)</td>
<td>4.5 (6.5)</td>
<td>3.7 (5.1)</td>
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<tr>
<td>Change (95% CI)</td>
<td>3.2 (0.9, 5.6)</td>
<td>3.2 (1.2, 5.2)</td>
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<tr>
<td>P value (within group)</td>
<td>0.007</td>
<td>0.003</td>
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**MID: Anchor-based approach**

<table>
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<tr>
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<th>Generic OIDP</th>
<th>Perio-Specific OIDP</th>
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<tr>
<td>Subjective periodontal health transition</td>
<td>4.6 (8.2)</td>
<td>5.3 (7.4)</td>
</tr>
<tr>
<td>Subjective oral health transition</td>
<td>4.9 (8.9)</td>
<td>5.7 (8.0)</td>
</tr>
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**MID: Distribution-based approach**

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<table>
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<tr>
<td>Effect size</td>
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<tr>
<td>Standardised Response Mean</td>
<td>0.41</td>
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<tr>
<td>Standard Error of Measurement</td>
<td>5.23</td>
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Assessing the minimally important difference in the Oral Impact on Daily Performances index in patients treated for periodontitis


Abstract

Aim: To assess changes over time and determine the minimally important difference (MID) in the Oral Impact on Daily Performances (OIDP) index for patients with severe generalized periodontal disease receiving periodontal treatment.

Methods: This study was nested in a larger randomized controlled trial and consisted of 45 consecutive subjects of the larger trial (17 receiving intensified and 28 receiving conservative periodontal care). The OIDP index assessed impacts on quality of life (QoL) at baseline and 1 month after treatment. Repeated-measures, ANOVA was used for comparison over time and between treatment groups. To estimate the MID, two subjective global transition scales, related to periodontal and oral health, respectively, were used as anchors, whereas the effect size (ES), standardized response mean and standard error of measurement were also calculated.

Results: The mean OIDP score after treatment was significantly lower than at baseline, indicating improvement in QoL. But there was no difference between treatment groups. Based on an agreement between different methods, the MID of the OIDP index was around five oral health dimensions and corresponded to a moderate ES.

Conclusions: The MID for the OIDP index among patients treated for severe generalized periodontitis provides meaning to change scores and facilitates interpretation of findings.

Patient-reported outcomes, such as oral health-related quality of life (OHQoL) measures, have scarcely been used in relation to periodontal diseases. The few relevant cross-sectional studies on other clinical practice patients or community sample participants have shown that periodontal conditions have a negative impact on the quality of their lives (Nashorn et al. 2004; Hig & Leong 2006; Cunha-Cruz et al. 2007, Lopez & Bachur 2007). Despite their limited use in periodontal research, such measures may provide valuable information in clinical practice, for example, for identifying treatment needs, selecting therapy, evaluating treatment outcomes and monitoring patient progress (Allen 2003, Locke 2004, Reiter & Pihl 2009). Although some clinical trials have reported that periodontal treatment resulted in significant improvement in patient’s quality of life (Cunha-Cruz et al. 2007; Aasland et al. 2009; Hig et al. 2009), these aspects provided no indication as to whether the improvement was clinically meaningful.

There are two potential reasons for the dearth of studies evaluating the effects of periodontal treatment on quality of life.
# Minimum Reporting standards for “OHRQoL” studies

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<th>Description</th>
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<td>Mean / Median</td>
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<tr>
<td>Alternative scoring formats</td>
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<td>Change scores distribution</td>
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<td><strong>Interpretation</strong></td>
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<td>Effect Size</td>
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<tr>
<td>Standardised Response Mean</td>
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<td>Standard Error of Measurement</td>
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<td>Global ratings</td>
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<td>Clinical benchmarks</td>
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THANK YOU!