Evaluating the responsiveness of the ICOAP following hip or knee replacement

Brief Report of Original Research

Introduction and Summary

Numerous measures of pain have been used clinically and in research in people with osteoarthritis (OA) of the hip. These most commonly include measures of pain intensity such as the numeric pain rating scale (1) and the Western Ontario McMaster Universities (WOMAC) pain subscale which measures pain on activity (2). However, recent work by Hawker and colleagues indicated that people with hip and knee OA experienced two distinct types of pain as OA progressed: a dull aching pain that is more consistent over time; and, intermittent pain that is often more intense, unpredictable and emotionally draining (3). Under the auspices of an OARSI/OMERACT initiative, the Intermittent and Constant Osteoarthritis Pain measure (ICOAP) was developed. Building on preliminary work demonstrating the reliability and validity of the ICOAP (4), this work evaluates the responsiveness of the ICOAP in people undergoing total hip (THR) and knee replacement (TKR). The ICOAP constant, intermittent and total scores demonstrate large effects as expected in this patient group with standardized response means (SRM) ranging from 0.80 to 2.31. Correlations of the change scores for the ICOAP, WOMAC, the Hip Disability and Osteoarthritis Outcome Score (HOOS) (5) and Knee Injury and Osteoarthritis Outcome Score (KOOS) (6) pain subscales and Chronic Pain Grade (CPG) (7,8) are moderate suggesting that the measures are evaluating different aspects of pain. This work further supports the growing body of evidence that the ICOAP is a valid and responsive measure for use in people with OA.
Methods, Results and Discussion

The participants in this study represent a subset of a larger cohort of people undergoing primary THR or TKR for OA recruited from four tertiary care centres in Toronto, Canada who were recruited between May 2006 and March 2008. Participants were eligible for the parent study if they were 18 years of age or older and were conversant in English such that they could consent to participate and complete the questionnaires. The sampled included in this study were recruited from December 2007 to March 2008 (n=78), the period in which the ICOAP was available. Data was collected pre-surgery and at six months follow-up by mailed questionnaire. The measures used in the current study included the ICOAP, WOMAC pain subscale, the HOOS or KOOS pain subscale and the CPG. Scores for all measures were standardized from 0-100 with 100 indicating worse pain. Descriptive data for the sample (THR: n=34; TKR: n=44) were calculated using means, standard deviations and proportions as appropriate. The standardized response mean (SRM) was calculated for each pain measure. The relative efficiency of measures was calculated as a ratio of SRMs where the ICOAP scores represented the comparator. Finally, Spearman correlation coefficients were calculated to evaluate the relationship of the change scores for the measures.

Table 1 presents the description of the sample which did not differ from the overall cohort (data not shown). As expected, there were more women than men who had TKR and the majority of people were overweight or obese. The average pain score, irrespective of the measure improved from pre-surgery to six months post surgery (Table 2). Of note, 50% of the THR and TKR patients reported that they had no constant pain as measured by the ICOAP at 6 months post surgery. As expected given the known effectiveness of hip and knee replacement surgery,
the standardized response means were large for the ICOAP and the other pain measures. As shown in Table 2, the SRM for the ICOAP scores range from 1.50 to 2.31 for THR and from 0.84 to 1.02 for TKR. The SRM was also large for the WOMAC, HOOS, KOOS and CPG for both THR and TKR. For all measures, the improvement was greater for the THR as compared to the TKR group. With the exception of the CPG, the relative efficiency (RE) indicates that the WOMAC pain and HOOS and KOOS pain detect greater change than the ICOAP (i.e., the RE is greater than 1). The correlation of the change scores showed different patterns and magnitudes for the THR as compared to TKR groups. For the THR group, constant pain had statistically significant correlations of 0.26, 0.34, and 0.39 for the CPG, HOOS and WOMAC respectively. The intermittent and total ICOAP pain scores had slightly higher associations ranging from 0.48 to 0.64 with the other pain measures. In contrast, the TKR group had correlations ranging from 0.66 to 0.81 for the various ICOAP scores with the other pain measures.

These data support that the ICOAP is responsive and able to detect the large improvements in pain that result from hip and knee replacement surgery. The smaller change in pain detected by all the measures for the TKR group as compared to the THR group is likely appropriate as it is accepted that, while the amount and rate of change is greatest in the first six months post surgery, THR patients have greater pain relief than TKR patients and TKR patients continue to improve beyond six months (9-11). Additionally, the SRMs are larger for the WOMAC pain subscale, HOOS and KOOS than for the ICOAP. From a research perspective, the implications of the magnitude of the SRM relates to the sample size for intervention studies. However, given the large change for each of the measures this is of less concern as the sample size requirements will be quite small irrespective of the measure. While the correlations of change indicate that there is an association among the pain measures, particularly for people undergoing TKR, these data
overall support prior work (4) that suggests that the ICOAP is measuring constructs of pain, not captured by the WOMAC, HOOS, KOOS or CPG. This is most notable for constant pain where the correlations for the THR group are very modest.

The sample sizes in this study are relatively small, although the anticipated changes post hip and knee replacement were observed. The sample is from a tertiary care setting and it is unclear that these results would be replicated in a sample from a community-based hospital; although Gandhi et al had demonstrated that the outcomes for those treated in academic as compared to community hospitals achieve similar results (12).

In addition to supporting the measurement properties of the ICOAP, the results of this study reinforce the need to carefully consider the outcome measure chosen in research studies. The construct of pain that is measured needs to be considered in the context of the question that is being asked and the implications for the data analysis may also need to be considered particularly if the question relates to understanding the relationship of pain to physical function. Measures such as the WOMAC, KOOS or HOOS which ask about pain on specified activity tend to be so highly associated with physical function that is difficult to evaluate the relationship (13-15).
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Author contributions

Conception and design: Davis, Lohmander, Hawker

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Critical revision of article: Davis, Lohmander, Wong, Venkataramanan, Hawker

Final approval of article: Davis, Lohmander, Wong, Venkataramanan, Hawker

Provision of study materials or patients: Hawker (ICOAP); Patients: Backstein, Davey, Gross, Mahomed, Schemitsch, Waddell

Statistical expertise: Davis, Lohmander, Venkataramanan, Hawker

Obtaining funding: Davis

Administrative, technical or logistic support: Wong

Collection and assembly of data: Davis, Wong

Role of the funding source

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Conflict of interest

None of the authors have any conflict of interest related to this work.
References


### Table 1: Sample descriptives

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<tr>
<th></th>
<th>THR (n=34)</th>
<th>TKR (n=44)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: mean, sd, range</td>
<td>58.2, 11.7, 37-85</td>
<td>64.2, 11.5, 45-86</td>
</tr>
<tr>
<td>Sex: Male/female</td>
<td>35/9 (74/26%)</td>
<td>11/33 (25/75%)</td>
</tr>
<tr>
<td>BMI: normal</td>
<td>8 (24%)</td>
<td>8 (18%)</td>
</tr>
<tr>
<td></td>
<td>12 (35%)</td>
<td>15 (36%)</td>
</tr>
<tr>
<td></td>
<td>13 (39%)</td>
<td>19 (45%)</td>
</tr>
<tr>
<td>Education: &gt; high school</td>
<td>25 (74%)</td>
<td>32 (73%)</td>
</tr>
</tbody>
</table>
Table 2: Pain measures\(^\ddagger\): At baseline, six months post surgery, mean change, standardized response mean (SRM) and relative efficiency (RE)

<table>
<thead>
<tr>
<th></th>
<th>Baseline mean (sd), median</th>
<th>Six months mean (sd), median</th>
<th>Change* mean (sd), median</th>
<th>SRM</th>
<th>RE** constant, intermittent, total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>THR (n=34)</strong></td>
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<tr>
<td>Constant pain</td>
<td>43.09 (24.80) 45</td>
<td>09.71 (18.17) 0</td>
<td>33.38 (22.21) 30</td>
<td>1.50</td>
<td></td>
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<tr>
<td>Intermittent pain</td>
<td>61.38 (16.31) 63</td>
<td>16.21 (19.86) 8</td>
<td>45.18 (19.56) 50</td>
<td>2.31</td>
<td></td>
</tr>
<tr>
<td>Total pain</td>
<td>53.09 (17.83) 56</td>
<td>13.32 (18.32) 6</td>
<td>39.76 (17.36) 34</td>
<td>2.29</td>
<td></td>
</tr>
<tr>
<td>WOMAC-pain</td>
<td>52.79 (14.10) 55</td>
<td>11.47 (12.94) 10</td>
<td>41.32 (15.87) 40</td>
<td>2.60</td>
<td>1.73, 1.13, 1.14</td>
</tr>
<tr>
<td>HOOS-pain</td>
<td>60.97 (13.35) 63</td>
<td>14.58 (13.98) 11</td>
<td>46.38 (15.51) 49</td>
<td>2.99</td>
<td>1.99, 1.29, 1.30</td>
</tr>
<tr>
<td>Chronic Pain Grade</td>
<td>60.84 (22.31) 59</td>
<td>12.21 (14.88) 11</td>
<td>48.26 (23.44) 48</td>
<td>2.05</td>
<td>1.36, 0.88, 0.90</td>
</tr>
<tr>
<td><strong>TKR (n=44)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Constant pain</td>
<td>42.27 (28.78) 50</td>
<td>15.45 (21.75) 0</td>
<td>26.82 (32.14) 22</td>
<td>0.84</td>
<td></td>
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<tr>
<td>Intermittent pain</td>
<td>52.25 (21.08) 54</td>
<td>23.66 (25.37) 13</td>
<td>28.59 (27.91) 29</td>
<td>1.02</td>
<td></td>
</tr>
<tr>
<td>Total pain</td>
<td>47.66 (23.12) 50</td>
<td>19.91 (20.93) 11</td>
<td>27.75 (27.22) 25</td>
<td>1.02</td>
<td></td>
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<tr>
<td>WOMAC-Pain</td>
<td>50.80 (20.96) 55</td>
<td>22.84 (20.78) 20</td>
<td>27.95 (23.24) 22</td>
<td>1.20</td>
<td>1.43, 1.18, 1.18</td>
</tr>
<tr>
<td>KOOS-Pain</td>
<td>58.25 (18.95) 58</td>
<td>28.09 (20.11) 26</td>
<td>30.16 (20.98) 28</td>
<td>1.44</td>
<td>1.71, 1.41, 1.41</td>
</tr>
<tr>
<td>Chronic Pain Grade</td>
<td>56.60 (26.10) 63</td>
<td>22.51 (23.58) 11</td>
<td>34.79 (30.84) 32</td>
<td>1.13</td>
<td>1.34, 1.11, 1.11</td>
</tr>
</tbody>
</table>

\(^\ddagger\)All scores range from 0-100 with 100 depicting greater pain
* Change – all positive scores depict improvement

** ICOAP, constant, intermittent and total scores respectively, served as the reference (denominator) in calculating RE
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