A New Highly Reliable Instrument for the Assessment of Pre- and Postoperative Gynecological Pain

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In this study, we evaluated the reliability of a newly developed method for pain assessment, which is based on perceptual matching by Pain Matcher®, Cefar Medical AB, Lund, Sweden, during minor gynecological surgery. In addition, the responsiveness to two different anesthetic methods—electro-acupuncture or a fast-acting opiate, alfentanil, both in combination with a paracervical block—was estimated by using Pain Matcher and visual analog scale (VAS) assessments before and 2 h after surgery. Two hundred-twenty-three women (aged 22–38 yr) participated. The results show that Pain Matcher is a reliable method for pain assessments, with lack of random individual disagreement and with no statistical evidence of systematic disagreement in position or in concentration. The augmented rank-order coefficient ($r$) values were excellent ($0.95–1.00$). When scales were used to detect true changes over time, there was no clear indication of responsiveness, mostly because of statistically significant random individual changes. However, the individual changes were much smaller for magnitude matching than for VAS. In conclusion, we would recommend the use of perceptual matching by Pain Matcher for pain assessment, because in this study it was a reliable and powerful in test-retest situations and had smaller individual changes than VAS after intervention. The Pain Matcher procedure was well accepted by the patients, and the results suggest that it may be useful when evaluating acute pre- and postoperative pain.

Optimal pain relief and anesthesia during a minor gynecological surgery, such as transvaginal ultrasound-guided oocyte aspiration during in vitro fertilization (IVF), is an important goal. Transvaginal follicle puncture requires one or two needle perforations through the vaginal wall to puncture the follicles in the ovary, lasts for approximately 20 to 30 min, and may be the most painful component of IVF treatment. The perceived pain during oocyte aspiration varies to a large extent from one individual to another and is often described in similar terms as intensive menstrual pain (1).

The visual analog scale (VAS) has traditionally been used as a method for evaluating the effectiveness of analgesia. The VAS is difficult to interpret, because two steps are involved: the patient’s pain rating and the clinician’s measurement of the patient’s line. Furthermore, the VAS is bounded by fixed end points and provides a limited range of measurement (2,3). It is also a limited way of assessing pain intensity, because the patient has to compare and grade perceived pain intensity against her worst-ever experience of pain (4).

The difficulties associated with the use of VAS and its phenomenon of a trimodal distribution have been previously reviewed (5). The VAS has a large number of categories, and its outcome may be influenced by false precision (6), which causes difficulties in detecting true changes in pain. The usefulness of VAS for the assessment of postoperative pain has been questioned by DeLoach et al. (7). They concluded that any individual determination with VAS has an imprecision of ±20 mm; this supports the theory of the false precision of the VAS. Because VAS is apparently not the “gold standard” that it was once thought to be, new methods for pain assessment are needed. An electrical stimulus against which the patient may match her perceived pain with nonvisualized predetermined end points is an alternative method for evaluating pain. Electrical stimulation has been previously used with few reported side effects in experimental situations for the measurement of sensory detection and pain thresholds (2,3). A recently developed perceptual matching device by Pain Matcher®, Cefar Medical AB,
Lund, Sweden, designed for clinical use in pain measurement, is based on electrical stimulation applied to the skin as a matching stimulus. This allows a continuous ordinal individual response with nonvisualized predetermined lower or upper limits. A recent study showed that perceptual matching by Pain Matcher has comparable reliability and responsiveness to the VAS (8).

Assessment of pain is often measured by rating scales, which can be defined as ordinal scaled data. We evaluate data statistically by a nonparametric rank-invariant method, because distances between categories do not represent any mathematical, numerical meaning, but only an order. Arithmetical methods may therefore lead to serious misinterpretations of the rating scales (7,9–11). All attempts at measures for correlation between repeated observations to estimate the level of agreement are false. The correlation coefficient measures only the level of association. Two measurements of VAS, for example, are expected to be associated, but the measure of interest here is the level of agreement (12).

The anesthetic method used during oocyte aspiration must have a rapid onset, provide optimal pain relief during the procedure, and allow a rapid recovery afterward. In Sweden, the most frequently used technique is a paracervical block (PCB) (13–17) in combination with IV opiates (18). Premedication with sedative drugs may be used. Studies on the pain-relieving effect of electro-acupuncture (EA) during surgery have been conducted, including one of oocyte aspiration during IVF treatment (19). EA was then shown to be as effective as conventional anesthetics.

The main goal of this study was to evaluate the reliability of a new method for pain measurement—perceptual matching by Pain Matcher—during a minor gynecological operation by using a rank-invariant statistical method. In addition, we estimated the responsiveness of Pain Matcher and VAS in the assessment of the acute pain before and 2 h after the operation as an effect of the two different anesthetic methods—EA or alfentanil—both applied in combination with a PCB.

Methods

Two-hundred-twenty-three women (aged 22–38 yr) participated in this prospective, randomized, multicenter study. All of them underwent IVF treatment with oocyte aspiration. This is the most painful component of IVF treatment, although most women also have abdominal pain as a result of their hormonal stimulation. The study was conducted at five IVF centers in Sweden (the IVF Unit at Sahlgrenska University Hospital in Göteborg; the Fertility Center Scandinavia in Göteborg; the IVF Center in Falun; the IVF Unit at Karolinska Hospital, Stockholm; and the International Fertility Center, Malmö).

Each woman gave written, informed consent before randomization to one of the two anesthetic methods. The study was approved by the ethics committees of Göteborg, Uppsala, Stockholm, and Lund Universities, Sweden.

The women were asked to rate their abdominal pain 30 min before and 2 h after oocyte aspiration. They were also asked to rate the present pain and worst pain experienced, directly related to and after the oocyte aspiration in the operating room. Two different pain measurement methods were used for the evaluation of pain in this clinical situation—a test with electrical stimulation of the skin, producing perceptual matching by Pain Matcher, and VAS—while the same questions were asked. The VAS ratings were recorded with a horizontal mark on a 100-mm line oriented vertically on a paper. Each VAS was scaled 0–100, with end points 0 (no pain) and 100 (worst pain). The perceptual matching with electrical stimulation was performed after each VAS rating, its having been shown previously that there are no order-related effects between different pain assessments (8). Pain Matcher estimates were recorded by two repeated observations. The woman was instructed to hold an electrode box between the thumb and index finger of the right hand. To increase the feeling of control, a hand switch was held in the left hand. The electrical stimulation unit was started by the assessor and delivered electrical pulses at a random velocity and with increasing intensity. When the sensation in the right hand corresponded in amplitude to her experienced pain, the woman was told to either press the hand switch or release her fingers from the electrode box, stopping the electrical stimulation. The value obtained, from 0 to 60, was automatically saved. The procedure was repeated within 15 to 30 s. The time to introduce, give instructions for, and perform the pain assessment was approximately the same for the two pain measurement methods.

The perceptual matching device, Pain Matcher, a unit that gives constant current stimulation, is controlled by a microprocessor that provides rectangular pulses with a frequency of 10 Hz and an amplitude of 10 mA. It is programmed to give a constant current stimulation despite variable skin resistance (e.g., influenced by sweating and anxiety of the subject) up to 13 kΩ. The intensifying of stimulation is achieved by successively increasing the pulse width from 0 to a possible maximum of 450 μs in increments of 7.5 μs, up to a total of 60 steps. The electrical charge per second is extremely low and varies through the different steps from 1.5 to 45 μC. The reached value (0–60) is directly related to the pulse width and is
The women in the group randomized to receive alfentanil were given 0.5 mg of alfentanil and 0.25 mg of atropine IV (Atropin NM Pharma, NM Pharma AB, Stockholm, Sweden) before the PCB was placed, directly before oocyte aspiration. The women in both groups could ask for additional alfentanil if EA or the initial dose of alfentanil did not produce sufficient pain relief.

All statistical calculations were performed with the software package SYRAN 1.0 for Matlab 6 (OrdStat AB, Stockholm, Sweden). To estimate the reliability between the first and second observations recorded by Pain Matcher, a statistical method was used without any assumption of underlying distribution and fitted to evaluate data as ordinal scaled data. The rank-invariant method was developed by E. Svenssson (11), and the following measures have been estimated: systematic disagreement for the group in position (RP) and in concentration (RC), level of random individual disagreement (RV), and the augmented rank-order coefficient ($r_a$) (6,7,9). A systematic disagreement common to the group, measured by RP and RC, indicates consistent disagreement between repeated assessments. The presence of individual disagreement, measured by RV, corresponds to the random part of the disagreement that could not be explained by the test-retest bias. An RV-related measure to express the size of random individual changes is the rank-order agreement coefficient, $r_a$ (6,7,9). The higher the value of $r_a$ between 0 and 1, the less the random part of the observed disagreement (6,11) and the lower the level of individual change, RV. For RV values, the possible interval is from 0 to 1, and a lower value represents less random disagreement. Values of RP and RC close to 0 indicate a lack of systematic disagreement. RP is equal to 1 if there is a complete positive shift to higher values in the assessments between two occasions. Negative RP values mean systematically lower recordings. Values of RC are positive if categorical distribution on the first occasion. In the evaluation of pain before and 2 h after oocyte aspiration, the pain assessments are evaluated by using the same statistical parameters, but the interpretation of RP corresponds to a systematic change in position: RC to a systematic change in concentration and RV to random individual changes. A positive change in position corresponds to increased thresholds for perceived pain values from the first to the second occasion, whereas a negative change in position corresponds to a decrease in the measured values.

<table>
<thead>
<tr>
<th>Time point for pain measurement</th>
<th>ALF ($n = 112$), median (range)</th>
<th>EA ($n = 111$), median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>VAS 4 (0–50), PM 4 (0–23)</td>
<td>VAS 4 (0–61), PM 4 (0–60)</td>
</tr>
<tr>
<td>Directly after operation—worst pain related to operation</td>
<td>VAS 48 (3–92), PM 12 (3–43)</td>
<td>VAS 53 (1–98), PM 12 (2–60)</td>
</tr>
<tr>
<td>Directly after operation—present pain</td>
<td>VAS 17 (0–81), PM 6 (1–40)</td>
<td>VAS 18 (0–73), PM 7 (0–60)</td>
</tr>
<tr>
<td>2 h after operation</td>
<td>VAS 15 (0–90), PM 4 (0–25)</td>
<td>VAS 10 (0–70), PM 4 (0–60)</td>
</tr>
</tbody>
</table>
Illustration of systematic disagreement for the group is performed by the relative operating characteristic (ROC) curve, and this is not to be confused with the more familiar ROC curve used for sensitivity and specificity evaluation (12). The two axes represent the cumulative proportions of the two repeated Pain Matcher measurements. Values of RP and RC close to 0 indicate negligible disagreement, and the corresponding ROC curve will be close to the main diagonal (6). A concave or convex ROC curve is a sign of systematic disagreement in the position of the scale, and an S-shaped ROC curve is a sign of systematic disagreement of concentration of the categories. The ROC curve was also used to demonstrate the systematic change over time, i.e., responsiveness. Values of RP and RC close to 0 indicate an absence of systematic changes. Statistical tests were two sided, and the level of significance was 0.05. RP, RC, and RV are presented together with their corresponding 95% confidence intervals.

Results

Table 1 shows the median and the range (minimum–maximum) for each pain measurement with Pain Matcher and VAS in the Alfentanil group and the EA group, respectively. Figure 1 shows the joint distribution between the first and the second Pain Matcher measurements recorded before oocyte aspiration in both groups. The ROC curves demonstrate the systematic disagreement for the group of the Pain Matcher measurements recorded before oocyte aspiration in the EA and the Alfentanil groups. The two ROC curves more or less follow the main diagonal. This indicates an absence of systematic disagreement in repeated pain assessments. Table 2 also shows the pattern of disagreement between repeated observations of perceived pain when using Pain Matcher before, directly after, and 2 h after the oocyte aspiration. The RP values and corresponding 95% confidence intervals showed no evidence for systematic disagreement in position at any time and were considered small. The results also show a lack of systematic disagreement in concentration (RC). The RV values indicate a lack of random individual disagreement in pain at all four assessments. The augmented rank-order agreement coefficient $r_a$ was excellent, from 0.953 to 0.998. These results indicate that perceptual matching by Pain Matcher is a reliable method.

Figure 2 shows the joint distribution between abdominal pain before oocyte aspiration and 2 h afterward, i.e., for Pain Matcher and VAS in the EA and the Alfentanil groups. The joint distribution shows a large spread of scatters both for VAS and for Pain Matcher, indicating considerable random individual changes. The ROC curves demonstrate the systematic group changes between abdominal pain before and 2 h after oocyte aspiration. Both VAS and Pain Matcher have a concave-shaped curve that corresponds to increased levels of pain assessment. Table 3 shows the pattern of changes in pain assessment before and 2 h after oocyte aspiration for Pain Matcher and VAS in the EA and the Alfentanil group. The outcome from the analysis of data indicates a systematic increase with respect to pain assessment in both the EA and the Alfentanil groups measured by Pain Matcher that was greater in the VAS assessments whose RP values showed statistical significance ($P < 0.05$). A systematic change in concentration was indicated both by Pain Matcher and by VAS. Statistically significant random individual changes were demonstrated by both methods of pain assessment but were much more obvious for
The presence of large random individual changes indicates a lack of responsiveness for both methods. The main result of this study was that perceptual matching by Pain Matcher showed excellent reliability, with a potential to capture a true responsiveness in the assessment of intensity of acute pain experienced before and after a minor gynecological operation. Two repeated observations displayed excellent agreement, which indicates that Pain Matcher is a reliable and efficient method of pain assessment.
was shown to be a highly reliable method of pain
assessment in patients with acute pain after a minor
gynecological operation. Pain Matcher in this setting is
easy to use and was well accepted. The results suggest
that electrical perceptual matching may be useful
when evaluating acute pre- and postoperative pain.

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### Table 3. The Measures of Group and Individual Changes in the Assessment of Acute Pain with Pain Matcher (PM) and Visual Analog Scale (VAS) in Response to Treatment (abdominal pain before – abdominal pain two hours after) for the Allentanil Group and the EA Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>PM</th>
<th>VAS</th>
<th>PM</th>
<th>VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic change for the group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In position</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RP (se)</td>
<td>0.103</td>
<td>0.353</td>
<td>0.114</td>
<td>0.179</td>
</tr>
<tr>
<td>95% CI</td>
<td>-0.020</td>
<td>0.215</td>
<td>-0.002</td>
<td>0.045</td>
</tr>
<tr>
<td>In concentration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RC (se)</td>
<td>0.186</td>
<td>0.115</td>
<td>0.047</td>
<td>0.214</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.045</td>
<td>-0.052</td>
<td>-0.087</td>
<td>0.054</td>
</tr>
<tr>
<td>Random individual changes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV (se)</td>
<td>0.361</td>
<td>0.820</td>
<td>0.358</td>
<td>0.637</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.199</td>
<td>1.022</td>
<td>0.199</td>
<td>0.467</td>
</tr>
<tr>
<td>Augmented rank-order agreement coefficient</td>
<td>0.639</td>
<td>0.180</td>
<td>0.642</td>
<td>0.363</td>
</tr>
</tbody>
</table>

CI = confidence interval; ALF = allentanil; EA = electro-acupuncture.

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