Validation of the Peak Day method of prospective determination of ovulation against a handheld urine hormone monitor

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**Introduction**

- Women can identify ovulation by systematic observation of changes in cervical mucus
- We developed Peak Day, a simplified self-education method
- Pilot: most women correctly applied the algorithm in their first cycle

**Objective**

Compare day of ovulation selected using the Peak Day algorithm to that identified using a blinded home fertility monitor

**Goal**

Demonstrate that Peak Day is a valid method for

1. Identifying ovulation
2. Timing concurrent or subsequent environmental exposure assessment in large, population-based cohorts of couples trying to conceive

**Methods**

- Recruited 17 female participants
  - Reproductive age
  - Trying to conceive
- Participants self-taught the Peak Day algorithm from our 3-page educational brochure
- Systematically observed and recorded their fertility signs for up to 2 menstrual cycles
- Selected their estimated day of ovulation using the Peak Day algorithm
- Concurrently tested their first morning urine each day using a modified ClearBlue® Easy fertility monitor
  - Blinded such that it provided no feedback to the user
  - LH surge on monitor determined ovulation
- Calculated sensitivity of Peak Day algorithm to monitor by comparing the dates of estimated days of ovulation

**Discussion**

- Challenges with LH monitor
  - Timing of daily test
  - Provide no feedback
- Learned towards end of study that test sticks from different lots could not be mixed for a single participant
  - Inaccurate readings
- Challenges with Peak Day algorithm
  - Some women noted fertile-quality premenstrual fluid
  - Specify mid-cycle cervical fluid to identify ovulation
  - Encourage measuring temperature to confirm ovulation
- Peak Day algorithm
  - *More sensitive & precise* than Day 14 or Knaus-Ogino Method
  - *Prospectively determines* ovulation

**Conclusion**

Peak Day is a novel and resource-efficient method for _prospective_ determination of ovulation.

Compared to home urine monitoring of LH, Peak Day detects ovulation +/-2 days with 81% sensitivity.

Allows for prospective environmental monitoring timed to periconceptional period and developmental windows rather than exposure recall.

Peak Day not precise enough for clinical diagnosis but identifying a 5-day window for ovulation is more precise than typical methods for population-based studies.

**Contact Information**

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**Peak Day Algorithm and Sample Chart**

<table>
<thead>
<tr>
<th>Day</th>
<th>Mucus Characteristics</th>
<th>Temperature Increase</th>
<th>Ovulation Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Clear</td>
<td>No</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>11</td>
<td>Clear</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>12</td>
<td>Clear</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>13</td>
<td>Clear</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
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<tr>
<td>14</td>
<td>Clear</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>15</td>
<td>Clear</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>16</td>
<td>Clear</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>17</td>
<td>Stretchy</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>18</td>
<td>Stretchy</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>19</td>
<td>Stretchy</td>
<td>Yes</td>
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</tr>
<tr>
<td>20</td>
<td>Stretchy</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
<tr>
<td>21</td>
<td>Stretchy</td>
<td>Yes</td>
<td>Confirmed by ClearBlue Easy Monitor</td>
</tr>
</tbody>
</table>

**PEAK DAY SENSITIVITY 81%**

Peak Day algorithm selected +/-2 days
17/21 cycles (81%)

Peak Day algorithm selected same day
4/21 cycles (19%)

**Participant observes and records**

- Presence of cervical fluid (Row 5)
- Characteristics of cervical fluid
  - Slippery (Row 6)
  - Clear (Row 6)
  - Stretchy (Row 8)

Peak Day is last day of any clear, slippery, or stretchy fluid that happens mid-cycle (Row 10)

Waking temperature optional but very helpful to confirm Peak Day

**Sensitivity Analysis**

<table>
<thead>
<tr>
<th>Ovulation Estimation Method</th>
<th>Sensitivity +/- 2 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Day</td>
<td>81% (17/21)</td>
</tr>
<tr>
<td>Modified Peak Day</td>
<td>86% (18/21)</td>
</tr>
<tr>
<td>Day 14</td>
<td>48% (10/21)</td>
</tr>
<tr>
<td>End of cycle - 14 days</td>
<td>55% (11/20)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ovulation Estimation Method</th>
<th>Sensitivity +/- 1 Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Day</td>
<td>52% (11/21)</td>
</tr>
<tr>
<td>Modified Peak Day</td>
<td>43% (9/21)</td>
</tr>
<tr>
<td>Day 14</td>
<td>48% (10/21)</td>
</tr>
</tbody>
</table>

**Participants self-taught the Peak Day algorithm to that identified using a blinded home fertility monitor**

**Sensitivity Analysis**

- Compared monitor results to
  - Peak Day Algorithm
  - Modified Peak Day Algorithm (accounts for fluid quality)
  - Day 14 ovulation
  - Knaus-Ogino Method

**Conclusion**

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**Acknowledgements**

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