Novel patient’s self-reporting diagnostic tool for premature ejaculation: development and validation.

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Introduction

• Premature ejaculation (PE) is one of the most common male sexual disorders (The highest prevalence rate of 31% (men aged 18-59 years) was found by the USA NHSLS study).

• In 1989 it was divided into two subgroups: primary (lifelong) PE and secondary (acquired) PE.

• There was no universally accepted definition of PE until recently.

• A novel unified definition was approved by the International Society of Sexual Medicine 2013.
Introduction

• Existing questionnaires: PEDT, PEP, AIPE, CIPE,
• However, European Association of Urology recognizes only two of them – Premature ejaculation diagnostic tool (PEDT) and Arabic Index of Premature Ejaculation (AIPE) as able to discriminate between patients who have PE and those who do not.
• Nevertheless none of existing PRO measure tools is irreproachable
Definition of PE

• The Second International Consultation on Sexual and Erectile Dysfunction defined PE as ‘ejaculation with minimal stimulation and earlier than desired, before or soon after penetration, which causes bother or distress, and over which the sufferer has little or no voluntary control’

McMahon CG, Abdo C, Incrocci L, et al. 2004
Objective

• We purposed to develop simple and accessible, valid and reliable self-assessment tool with appropriate of sensitivity, specificity and diagnostic value for evaluating patients suffering from PE, which could improve the accuracy of diagnosis of PE.
Development of the questionnaire

- Literature search
- Development of multiple-choice questions and the answers to them.
- Translation to Russian.
- Designing the questionnaire.
- Pilot test.
Translational process

- Conceptual definition.
- Forward translation.
- Reconciliation.
- Version 1.
- Backward translation.
- Comparison.
- Version 2.
- Pilot test and approval of the final version of the questionnaire.
Study population

- 25 sexually active heterosexual male respondents
- The age of respondents varied from 21 to 57 and mean age (Mean ± SD) was 32.6 ± 8.7 years.
- All respondents could speak and read Russian fluently.
- Before answering to the questionnaire, respondents were informed about the meaning of the terms as intravaginal ejaculation latency time (IELT) and premature ejaculation defined by American Psychiatric Association.
Statistical methods

- **Reliability**: Cronbach's alpha, intraclass correlation coefficient, and Spearman-Brown split-half coefficient.
- **Convergent validity**: correlation of each item’s score of the questionnaire with a total score.
- **Sensitivity and specificity**: area under the curve (AUC) using the ROC-curve analysis. The "yes" answer when using a dichotomous scale (unpublished data) was taken as a positive state variable for this test.
- **Discriminative ability**: known-groups validity. Respondents were divided into two groups in dependence of to their answer when using dichotomous scale.
- Nonparametric Mann-Whitney U test was used for comparison of scores between groups.
- **Strength of relations**: Spearman’ rank correlation coefficient (rho).
- *P* value lower than 0.05 was considered as significant.
Results

• Of them 16 were excluded from further consideration.
• Multiple-choice questions and answers to them were developed using selected literature data.
• Developed multi-choice questions and answers to them were ordered and underwent the process of translation.
<table>
<thead>
<tr>
<th>1.</th>
<th>Оцените в баллах, насколько сложным является для вас задержать (контролировать) наступление эякуляции?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ A  несложно, могу контролировать                                      0</td>
</tr>
<tr>
<td></td>
<td>□ B  бывает немного сложно                                             1</td>
</tr>
<tr>
<td></td>
<td>□ C  затруднительно                                                    2</td>
</tr>
<tr>
<td></td>
<td>□ D  очень сложно                                                       3</td>
</tr>
<tr>
<td></td>
<td>□ E  невозможно                                                        4</td>
</tr>
<tr>
<td>2.</td>
<td>Как часто у вас эякуляция происходит ранее желаемого момента?</td>
</tr>
<tr>
<td></td>
<td>□ A  почти никогда или крайне редко                                      0</td>
</tr>
<tr>
<td></td>
<td>□ B  меньше чем в половине случаев                                      1</td>
</tr>
<tr>
<td></td>
<td>□ C  примерно в половине случаев                                        2</td>
</tr>
<tr>
<td></td>
<td>□ D  больше чем в половине случаев                                      3</td>
</tr>
<tr>
<td></td>
<td>□ E  почти всегда или всегда                                            4</td>
</tr>
<tr>
<td>3.</td>
<td>Как часто у вас эякуляция происходит преждевременно (в самом начале вагинального проникновения)?</td>
</tr>
<tr>
<td></td>
<td>□ A  иногда или редко                                                   0</td>
</tr>
<tr>
<td></td>
<td>□ B  меньше чем в половине случаев                                      1</td>
</tr>
<tr>
<td></td>
<td>□ C  примерно в половине случаев                                        2</td>
</tr>
<tr>
<td></td>
<td>□ D  больше чем в половине случаев                                      3</td>
</tr>
<tr>
<td></td>
<td>□ E  почти всегда или всегда                                            4</td>
</tr>
<tr>
<td>4.</td>
<td>Длительность полового акта (от проникновения до момента эякуляции)</td>
</tr>
<tr>
<td></td>
<td>□ A  от 7-14 минут и более                                             0</td>
</tr>
<tr>
<td></td>
<td>□ B  от 3 до 6 минут                                                   1</td>
</tr>
<tr>
<td></td>
<td>□ C  от 1 до 2 минут                                                   2</td>
</tr>
<tr>
<td></td>
<td>□ D  менее 1 минут                                                     3</td>
</tr>
<tr>
<td></td>
<td>□ E  до 30 секунд                                                      4</td>
</tr>
<tr>
<td>5.</td>
<td>Преждевременная эякуляция возникает только при смене партнерши?</td>
</tr>
<tr>
<td></td>
<td>□ A  возникает очень редко и только при смене партнерши, с постоянной все нормально                                   0</td>
</tr>
<tr>
<td></td>
<td>□ B  иногда возникает при смене партнерши                               1</td>
</tr>
<tr>
<td></td>
<td>□ C  в половине случаев при смене партнерши                            2</td>
</tr>
<tr>
<td></td>
<td>□ D  больше чем в половине случаев при смене партнерши                 3</td>
</tr>
<tr>
<td></td>
<td>□ E  нет, не только, случается даже с постоянной партнершей            4</td>
</tr>
<tr>
<td>6.</td>
<td>Считаете ли вы, что ваша партнерша удовлетворена сексуальной жизнью</td>
</tr>
<tr>
<td></td>
<td>□ A  да, вполне                                                        0</td>
</tr>
<tr>
<td></td>
<td>□ B  больше «да», чем «нет»                                             1</td>
</tr>
<tr>
<td></td>
<td>□ C  примерно в половине случаев                                       2</td>
</tr>
<tr>
<td></td>
<td>□ D  больше «нет», чем «да»                                            3</td>
</tr>
<tr>
<td></td>
<td>□ E  нет                                                              4</td>
</tr>
<tr>
<td>7.</td>
<td>Испытываете ли вы до или во время полового акта тревогу, беспокойство</td>
</tr>
<tr>
<td></td>
<td>□ A  нет (никогда)                                                     0</td>
</tr>
<tr>
<td></td>
<td>□ B  редко, незначительно                                              1</td>
</tr>
<tr>
<td></td>
<td>□ C  бывает, но не всегда                                              2</td>
</tr>
<tr>
<td></td>
<td>□ D  очень часто                                                       3</td>
</tr>
<tr>
<td></td>
<td>□ E  всегда                                                            4</td>
</tr>
<tr>
<td>8.</td>
<td>Беспокоит ли вас то, что эякуляция происходит быстрее, чем вы хотели бы?</td>
</tr>
<tr>
<td></td>
<td>□ A  нет (никогда)                                                     0</td>
</tr>
<tr>
<td></td>
<td>□ B  немного беспокоит, иногда                                         1</td>
</tr>
<tr>
<td></td>
<td>□ C  примерно в половине случаев                                       2</td>
</tr>
<tr>
<td></td>
<td>□ D  очень                                                             3</td>
</tr>
<tr>
<td></td>
<td>□ E  чрезвычайно (всегда)                                              4</td>
</tr>
</tbody>
</table>

Общий балл =
Reliability and validity

- Cronbach’s alpha - 0.88 (0.8-0.94).
- Spearman-Brown coefficient - 0.87,
- Guttman’ split-half coefficient - 0.86;
- Cronbach's alpha 0.75, and 0.84 for the first and second halves of the questionnaire respectively.
- Correlation between forms was 0.8.
- Spearman’s rho between items was straight and strong and varied from 0.63 to 0.86.
Compare sum of scores between groups

- Control: n=13
- Main: n=12
ROC-curve analysis
Summary

- Pilot test resulted in development of self assessing questionnaire which can potentially reveal men suffering from PE;
- Analysis of reliability of our questionnaire resulted in good values (Cronbach’s alpha- 0.88, Guttman’ split-half coefficient - 0.86 etc);
- Sensitivity of the tool is also very good;
- However it should be tested in wider cohort before being recommended for widely use.
Thank you for your attention!
References

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