

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

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# Introduction

- Premature ejaculation (PE) is one of 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'*

# 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  $\pm$  SD) was  $32.6 \pm 8.7$  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

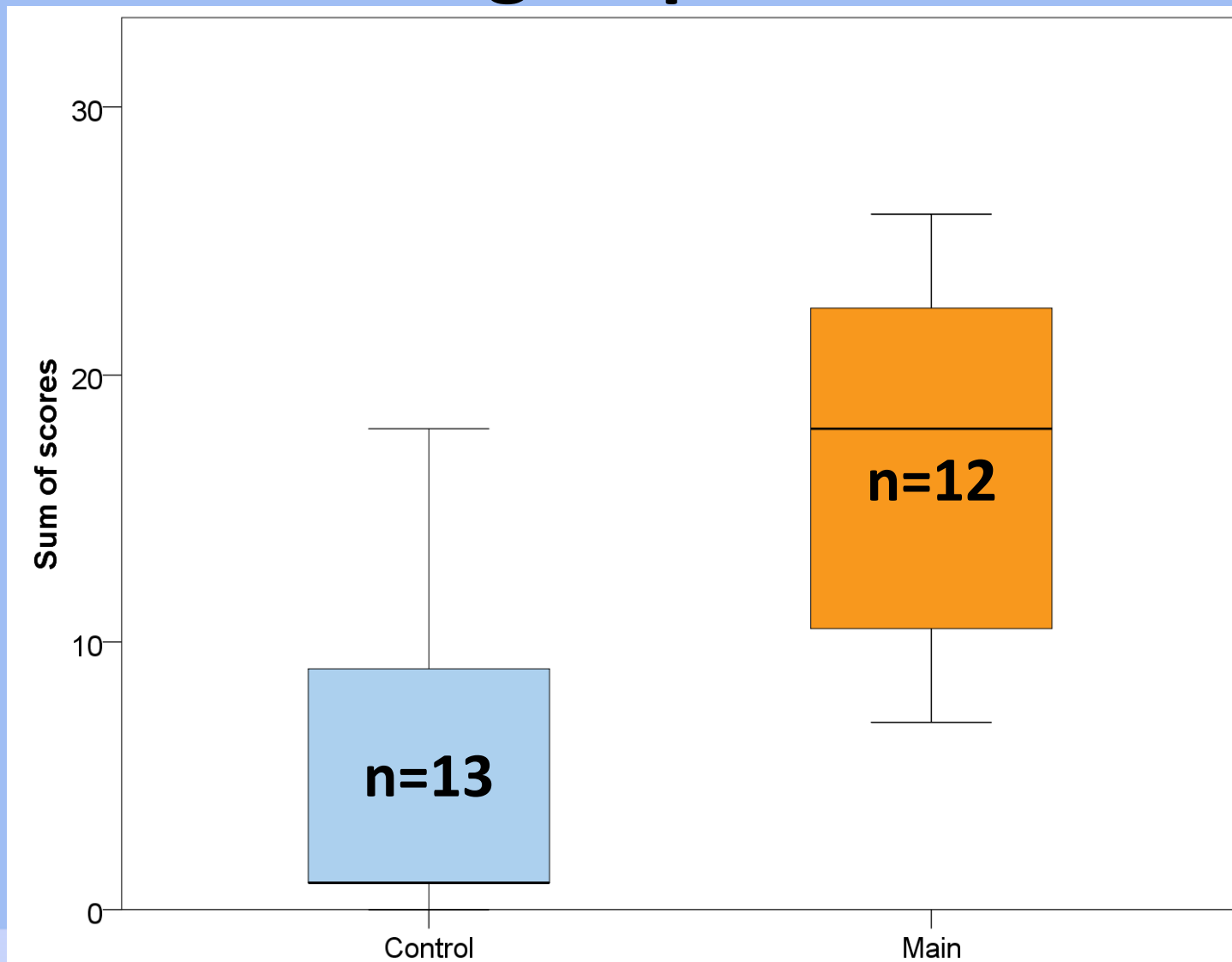
- Literature search - 31 English-language articles published in the period from 1981 until 2014.
- Of them 16 were excluded from further consideration.
- Multiple-choice questions and answers to them were developed using selected literature data.
- Developed multi-choice questions and answers to them were ordered and underwent the process of translation.

<b>1. Оцените в баллах, насколько сложным является для вас задержать (контролировать) наступление эякуляции?</b>			
<input type="checkbox"/>	A	несложно, могу контролировать	0
<input type="checkbox"/>	B	бывает немного сложно	1
<input type="checkbox"/>	C	затруднительно	2
<input type="checkbox"/>	D	очень сложно	3
<input type="checkbox"/>	E	невозможно	4
<b>2. Как часто у вас эякуляция происходит ранее желаемого момента?</b>			
<input type="checkbox"/>	A	почти никогда или крайне редко	0
<input type="checkbox"/>	B	меньше чем в половине случаев	1
<input type="checkbox"/>	C	примерно в половине случаев	2
<input type="checkbox"/>	D	больше чем в половине случаев	3
<input type="checkbox"/>	E	почти всегда или всегда	4
<b>3. Как часто у вас эякуляция происходит преждевременно (в самом начале вагинального проникновения)?</b>			
<input type="checkbox"/>	A	иногда или редко	0
<input type="checkbox"/>	B	меньше чем в половине случаев	1
<input type="checkbox"/>	C	примерно в половине случаев	2
<input type="checkbox"/>	D	больше чем в половине случаев	3
<input type="checkbox"/>	E	почти всегда или всегда	4
<b>4. Длительность полового акта (от проникновения до момента эякуляции)</b>			
<input type="checkbox"/>	A	от 7-14 минут и более	0
<input type="checkbox"/>	B	от 3 до 6 минут	1
<input type="checkbox"/>	C	от 1 до 2 минут	2
<input type="checkbox"/>	D	менее 1 минуты	3
<input type="checkbox"/>	E	до 30 секунд	4
<b>5. Преждевременная эякуляция возникает только при смене партнерши?</b>			
<input type="checkbox"/>	A	возникает очень редко и только при смене партнерши, с постоянной все нормально	0
<input type="checkbox"/>	B	иногда возникает при смене партнерши	1
<input type="checkbox"/>	C	в половине случаев при смене партнерши	2
<input type="checkbox"/>	D	больше чем в половине случаев при смене партнерши	3
<input type="checkbox"/>	E	нет, не только, случается даже с постоянной партнершей	4
<b>6. Считаете ли вы, что ваша партнерша удовлетворена сексуальной жизнью</b>			
<input type="checkbox"/>	A	да, вполне	0
<input type="checkbox"/>	B	больше «да», чем «нет»	1
<input type="checkbox"/>	C	примерно в половине случаев	2
<input type="checkbox"/>	D	больше «нет», чем «да»	3
<input type="checkbox"/>	E	нет	4
<b>7. Испытываете ли вы до или во время полового акта тревогу, беспокойство</b>			
<input type="checkbox"/>	A	нет (никогда)	0
<input type="checkbox"/>	B	редко, незначительно	1
<input type="checkbox"/>	C	бывает, но не всегда	2
<input type="checkbox"/>	D	очень часто	3
<input type="checkbox"/>	E	всегда	4
<b>8. Беспокоит ли вас то, что эякуляция происходит быстрее, чем вы хотели бы?</b>			
<input type="checkbox"/>	A	нет (никогда)	0
<input type="checkbox"/>	B	немного беспокоит, иногда	1
<input type="checkbox"/>	C	примерно в половине случаев	2
<input type="checkbox"/>	D	очень	3
<input type="checkbox"/>	E	чрезвычайно (всегда)	4
<b>Общий балл=</b>			

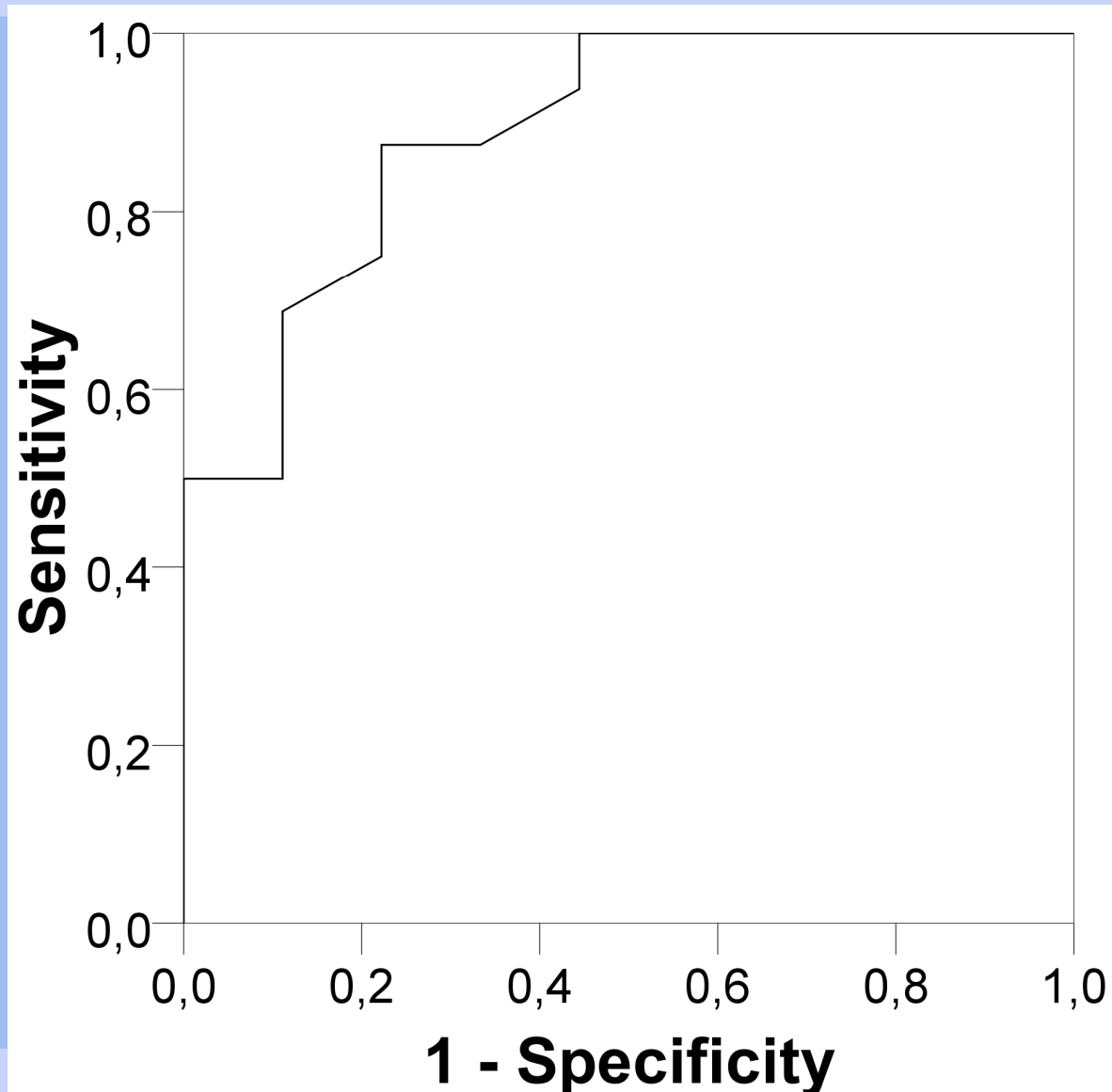
# Reliability and validity

- 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



# 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

- Abraham L, Symonds T, Morris MF (2008) Psychometric validation of a sexual quality of life questionnaire for use in men with premature ejaculation or erectile dysfunction. *The journal of sexual medicine* 5:595-601
- Acquadro C, Conray K, Giroudet C et al. (2004) *Linguistic Validation Manual for Patient-Reported Outcomes (PRO) Instruments*. Kluwer Academic Publishers, Mapi Research Institute, Lyon, France
- Althof S, Rosen R, Symonds T et al. (2006) Development and validation of a new questionnaire to assess sexual satisfaction, control, and distress associated with premature ejaculation. *The journal of sexual medicine* 3:465-475
- Althof SE, Abdo CH, Dean J et al. (2010) International Society for Sexual Medicine's guidelines for the diagnosis and treatment of premature ejaculation. *The journal of sexual medicine* 7:2947-2969
- Althof SE, McMahon CG, Waldinger MD et al. (2014) An update of the International Society of Sexual Medicine's guidelines for the diagnosis and treatment of premature ejaculation (PE). *The journal of sexual medicine* 11:1392-1422
- Althof SE, Symonds T (2007) Patient reported outcomes used in the assessment of premature ejaculation. *The Urologic clinics of North America* 34:581-589, vii
- American Psychiatric Association. (2000) *Diagnostic criteria from DSM-IV-TR*. American Psychiatric Association, Washington, D.C.
- Arafa M, Shamloul R (2007) Development and evaluation of the Arabic Index of Premature Ejaculation (AIPE). *The journal of sexual medicine* 4:1750-1756

# References

- Broderick GA (2006) Premature ejaculation: on defining and quantifying a common male sexual dysfunction. *The journal of sexual medicine* 3 Suppl 4:295-302
- European Association of Urology Guideline G (2014) EAU Guidelines, edition presented at the 29th EAU Annual Congress, Stockholm.
- Gao J, Zhang X, Su P et al. (2013) Prevalence and factors associated with the complaint of premature ejaculation and the four premature ejaculation syndromes: a large observational study in China. *The journal of sexual medicine* 10:1874-1881
- Giuliano F, Patrick DL, Porst H et al. (2008) Premature ejaculation: results from a five-country European observational study. *European urology* 53:1048-1057
- Godpodinoff ML (1989) Premature ejaculation: clinical subgroups and etiology. *Journal of sex & marital therapy* 15:130-134
- Janssen PK, Bakker SC, Rethelyi J et al. (2009) Serotonin transporter promoter region (5-HTTLPR) polymorphism is associated with the intravaginal ejaculation latency time in Dutch men with lifelong premature ejaculation. *The journal of sexual medicine* 6:276-284
- Jern P, Piha J, Santtila P (2013) Validation of three early ejaculation diagnostic tools: a composite measure is accurate and more adequate for diagnosis by updated diagnostic criteria. *PloS one* 8:e77676
- Kaufman JM, Rosen RC, Mudumbi RV et al. (2009) Treatment benefit of dapoxetine for premature ejaculation: results from a placebo-controlled phase III trial. *BJU international* 103:651-658

# References

- Laumann EO, Nicolosi A, Glasser DB et al. (2005) Sexual problems among women and men aged 40-80 y: prevalence and correlates identified in the Global Study of Sexual Attitudes and Behaviors. *International journal of impotence research* 17:39-57
- Laumann EO, Paik A, Rosen RC (1999) Sexual dysfunction in the United States: prevalence and predictors. *JAMA : the journal of the American Medical Association* 281:537-544
- McMahon CG (2007) Ejaculatory latency vs. patient-reported outcomes (PROs) as study end points in premature ejaculation clinical trials. *European urology* 52:321-323
- McMahon CG, Althof S, Waldinger MD et al. (2008) An evidence-based definition of lifelong premature ejaculation: report of the International Society for Sexual Medicine Ad Hoc Committee for the Definition of Premature Ejaculation. *BJU international* 102:338-350
- Melnik T, Althof S, Atallah AN et al. (2011) Psychosocial interventions for premature ejaculation. *The Cochrane database of systematic reviews*:CD008195
- Montorsi F (2005) Prevalence of premature ejaculation: a global and regional perspective. *The journal of sexual medicine* 2 Suppl 2:96-102
- Organization. WH (1994) *International Classification of Diseases and Related Health Problems*.
- Patrick DL, Althof SE, Pryor JL et al. (2005) Premature ejaculation: an observational study of men and their partners. *The journal of sexual medicine* 2:358-367

# References

- Patrick DL, Giuliano F, Ho KF et al. (2009) The Premature Ejaculation Profile: validation of self-reported outcome measures for research and practice. *BJU international* 103:358-364
- Read S, King M, Watson J (1997) Sexual dysfunction in primary medical care: prevalence, characteristics and detection by the general practitioner. *Journal of public health medicine* 19:387-391
- Rosen RC, Catania JA, Althof SE et al. (2007) Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. *Urology* 69:805-809
- Rosenberg MT, Sadosky R (2007) Identification and diagnosis of premature ejaculation. *International journal of clinical practice* 61:903-908
- Rowland DL (1998) A psychophysiological approach to assessing premature ejaculation. *International journal of impotence research* 10 Suppl 2:S44-48; discussion S49-51
- Serefoglu EC, McMahon CG, Waldinger MD et al. (2014) An evidence-based unified definition of lifelong and acquired premature ejaculation: report of the second International Society for Sexual Medicine Ad Hoc Committee for the Definition of Premature Ejaculation. *The journal of sexual medicine* 11:1423-1441
- Shabsigh R (2006) Diagnosing premature ejaculation: a review. *The journal of sexual medicine* 3 Suppl 4:318-323
- Solursh DS, Ernst JL, Lewis RW et al. (2003) The human sexuality education of physicians in North American medical schools. *International journal of impotence research* 15 Suppl 5:S41-45

# References

- Sotomayor M (2005) The burden of premature ejaculation: the patient's perspective. *The journal of sexual medicine* 2 Suppl 2:110-114
- Sperber AD (2004) Translation and validation of study instruments for cross-cultural research. *Gastroenterology* 126:S124-128
- Symonds T, Perelman M, Althof S et al. (2007) Further evidence of the reliability and validity of the premature ejaculation diagnostic tool. *International journal of impotence research* 19:521-525
- Symonds T, Perelman MA, Althof S et al. (2007) Development and validation of a premature ejaculation diagnostic tool. *European urology* 52:565-573
- Waldinger MD, Quinn P, Dilleen M et al. (2005) A multinational population survey of intravaginal ejaculation latency time. *The journal of sexual medicine* 2:492-497
- Wang W, Kumar P, Minhas S et al. (2005) Proposals or findings for a new approach about how to define and diagnose premature ejaculation. *European urology* 48:418-423
- Wild D, Eremenco S, Mear I et al. (2009) Multinational trials-recommendations on the translations required, approaches to using the same language in different countries, and the approaches to support pooling the data: the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force report. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 12:430-440
- Wild D, Grove A, Martin M et al. (2005) Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 8:94-104
- Yuan YM, Xin ZC, Jiang H et al. (2004) Sexual function of premature ejaculation patients assayed with Chinese Index of Premature Ejaculation. *Asian journal of andrology* 6:121-126