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ARTICLE

Men with subjective premature ejaculation have a similar lognormal IELT distribution as men in the general male population and differ mathematically from males with lifelong premature ejaculation after an IELT of 1.5 minutes (Part 2)

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Abstract

Men with Subjective premature ejaculation (PE) have complaints of PE but have normal intravaginal ejaculation latency time (IELT) durations. We found two previously published large epidemiological stopwatch-mediated IELT studies to encompass IELT details of men with Subjective PE, albeit this term was not mentioned in both studies or in reviews of them. In the current study we developed the mathematical formula of the IELT distribution of men with complaints of PE, as diagnosed by a clinician on basis of the DSM-IV-TR definition of PE, as reported in the two studies performed in the USA and Europe, respectively. The formula was calculated by investigation of the fitness of various well-known mathematical Probability Density distributions into the IELT distribution of the PE men and non-PE men of the two studies. The better the fitness the lower is the Goodnes of Fit (GOF). Another aim of the study was to investigate whether the IELT distribution of men with "complaints" of PE (Subjective PE) differs mathematically from the IELT distribution of the general male population and that of Lifelong PE. The overlap of the area under the curve (AUC) of the IELT distribution of the men with PE complaints and that of the general male population was calculated together with the cut-off point at which the AUC equals 10%. We found that the IELT distributions of the PE men in both studies were Lognormal distributions and that at the cut-off point at which the AUC is equal to 10% ($p = 0.10$) the IELT is 1.5 min, indicating that after 1.5 min the IELT distribution of males with complaints of PE becomes mathematically identical to that of the general male population. In conclusion, there is hard mathematical evidence that the IELT distribution of men with complaints of PE with normal IELT values (e.g., the Lognormal IELT distribution of Subjective PE) and the IELT distribution of men with Lifelong PE (e.g. the Gumbel Max IELT distribution) belong to two independent populations. According to the applied mathematical calculations Subjective PE starts after an IELT of 1.5 min and encompasses all higher IELT values. It may imply that the current IELT cut-off point in Lifelong PE should be 1.5 min instead of the approximate 1 min, as has previously been stated by ISSM and DSM 5.

Introduction

Recently, Waldinger and Schweitzer [1, 2] have argued that the use of a stopwatch to measure intravaginal ejaculation latency time (IELT) is of utmost importance in males with

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Lifelong PE, defined in term of an IELT of less than 1 min. However, they also explained that in males with Subjective PE, defined in terms of an IELT of around 5–6 min, the measurement of the characteristic features of Subjective PE requires another objective measure [1–3]. For example, the core issue of Lifelong PE is the male's very short IELT with the minimal variation of sexual performance during intercourse, whereas Subjective PE is characterized by a higher variation of sexual performance and longer IELT values during intercourse [1, 2]. Measurement of the IELT by a stopwatch is most adequate to show pathology of the IELT when variation of sexual performance is minimal, such as occurs in men with Lifelong PE who usually ejaculate within seconds. However, measurement of the recently suggested measure "Intravaginal Thrusting Variation Performance", which consists of various parameters of penile intravaginal thrusting, is more representative of sexual activity in case of higher variation in sexual performance, as is the case in Subjective PE [1, 2]. Nevertheless, also IELT stopwatch studies may show the existence of Subjective PE.

Although Subjective PE is a new concept, we have found that for many years two very large and well-known stopwatch-mediated IELT studies contain the data demonstrating the existence of Subjective PE, albeit this term has not been mentioned in both studies or in reviews of both studies. Indeed, in the two epidemiological IELT stopwatch studies in the USA by Patrick et al. [4] and in Europe by Giuliano et al. [5] the IELT has been measured in men with complaints of PE with normal IELT values, as diagnosed by a clinician on the basis of the DSM-IV-TR [6] definition of PE. In the current study, we argue that these men with complaints of PE and normal IELT values have Subjective PE.

In a previous study [7] and in Part 1 of the current study, Janssen and Waldinger [8] have shown that by transforming a stopwatch-mediated IELT distribution curve into a mathematical representation of such an original IELT distribution, the IELT distribution of men in the general male population have a Lognormal IELT distribution, whereas the IELT distribution of Lifelong PE is a Gumpel Max Distribution. Janssen and Waldinger [7, 8] noted that the stopwatch-measured IELT studies of large cohorts of men in the general male population, as published by Waldinger et al. [9, 10], Patrick et al. [4] and Giuliano et al. [5], do not provide the required hard data to precisely calculate the IELT distribution of men with Lifelong PE as there are firstly hardly any males with IELTs of less than 1 min in the general male population, and secondly, separate IELT values have not been mentioned in these studies [7]. Therefore, the currently only possible way to perform precise IELT research with sufficient men with Lifelong PE is to perform such a study in a consecutive clinical cohort of men with Lifelong PE, as has been published by Waldinger et al. in 1998 [11].

In Part 1 of the current study [8], we have shown that the IELT distribution in the general male population of the USA (Patrick et al. study [4]) and in Europe (e.g., France, Italy, Germany, Poland and UK) (Giuliano et al. study [5]) has the same mathematical, e.g. Lognormal, IELT distribution, as has previously been found in a random group of men in the general population in five countries (The Netherlands, UK, Spain, Turkey and USA) (Waldinger et al. studies) [9, 10]. The three IELT Lognormal distributions of men in the general male population in the USA and Europe differed mathematically van the Gumbel Max IELT distribution in men with Lifelong PE, as was found in a previous study [4, 5, 9–11].

In Part 2 of the current study, the aim was to investigate whether the mathematically transformed orignal IELT distribution of men with "complaints" of PE differs from the the mathematically transformed orignal IELT distribution of the general male population. This could be calculated as the studies of Patrick et al. [4] and Giuliano et al. [5] distinguish men with complaints of PE versus men without complaints of PE (e.g., non-PE men) on the basis of PE diagnosis of a clinician according to DSM-IV-TR criteria [6].

The clinical importance of the current study using this mathematical approach of the original IELT distribution of different stopwatch-measured IELT studies is that it provides data to show that Subjective PE is not only clinically but also mathematically a different PE disorder compared to Lifelong PE. As men with Subjective PE have normal IELT values, we postulated that in the current study the IELT distribution of men with complaints of PE but with normal IELT durations, e.g. Subjective PE, would mathematically not differ from the IELT distribution of men in the general male population. Based on this assumption it is also postulated that the IELT distribution of men with Subjective PE will mathematically differ from the IELT distribution of males with Lifelong PE.

Materials and methods

For research of data one needs raw data. However, in scientific research of data that have been published by other researchers it is often impossible to get their raw data. Interestingly, in spite of this limitation, it is possible to derive raw data of others by applying a mathematical method on the published data distribution curve provided by the other researchers. In the current study, we have applied this method to the research of two IELT studies, published by Patrick et al. [4] and Giuliano et al. [5] in 2005 and 2008, respectively. In addition, we have used the same method on three previously published studies by Waldinger et al. [9–11]. The method encompasses the following strategy:

First, with knowledge of the total population number (e.g., number of men), provided by the study, it is possible to calculate the absolute number of the IELT data from the provided percentages of each IELT subpopulation. These absolute IELT numbers are then transformed to a table. This table of IELTs will be used as raw data for further calculations of these data. For example, in a study of 182 men with PE a subpopulation of 6,04% of men have an IELT of 1 to 1.5 min. This means that the absolute number of these men with an IELT of 1 to 1.5 min is 0.0604 times 182 = 11. By application of the statistical programme Easy Fit Professional ver. 56 (Mathwave Technologies Inc.) [12], we analysed the IELT data of two previously published stopwatch studies of the IELT in a cohort of men that were distinguished in having "complaints of PE" and having "no complaints of PE" on the basis of a PE diagnosis by a clinician using DSM-IV-TR criteria [4–6]. In addition, and similar to our two previous studies [8, 11], we investigated which of the well-known mathematical Probability Density distributions fitted most accurately to the curves of the aforementioned IELT distributions according to a specific mathematical formula. The fitness of this mathematical formula and associated mathematical Probability Density distribution into the original IELT distribution is calculated by the Kolmogorov–Smirnov test (KS test) and expressed by the Goodness of Fit (GOF) [13, 14]. The GOF therefore is a measure for the accuracy of the fitness [13, 14]. The smaller the GOF, the better the fitness, and the better the Probability Density Distribution represents the original IELT distribution. The smaller the difference between the theoretical mathematical distribution and the actual IELT distribution, the more accurate is the fitness of the theoretical distribution on the original IELT distributon.

The KS test is a nonparametric statistical test of the equality of continuous one-dimensional probability distributions [13, 14]. The KS test was used to compare the IELT distributions with various well-known theoretical reference Probability Density distributions (one-sample KS test).

In order to investigate a potential (mathematical) difference in the IELT distribution between the group of men with complaints of PE and the general male population (= PE males + non-PE males) in the studies of Patrick et al. [4] and Giuliano et al. [5], we applied the mathematical formulas of the Probability Density Function of the IELT distributions of the males with complaints of PE and the general male population and calculated the overlap between the area under the curve (AUC) of the IELT distribution of the general male population with the AUC of the IELT distribution and the males with complaints of PE. The cut-off point of this overlap is the point at which the AUC equals 10%. After this point ($p = 0.10$) both populations become identical.

Results

Tables 1a and 2a show the number of men in the combined random cohort study of Waldinger as published in 2005 and 2009 [9, 10] ($n = 965$), the PE and non-PE men study of Patrick et al., as published in 2005 [4] ($n = 1587$) and the PE and non-PE men study of Giuliano et al., as published in 2008 [5] ($n = 1115$), with the median IELT, mean IELT, the number and percentage of males with an IELT of <1 min, and the range of the IELT.

However, as in the Patrick et al. [4] and Giuliano et al. [5] studies not all participating males used a stopwatch, we only performed mathematical calculations on the number of males that used a stopwatch in these studies.

Figure 1a, b shows the Probability Density Function and associated formula of men with complaints of PE, as reported by Patrick et al. [4] and Giuliano et al. [5], respectively. The Lognormal Probability Density distribution fitted most well on the IELT distributions of the men with complaints of PE and of the men without complaints of PE in both studies. According to Kolmogorov and Smirnov the GOF of the Lognormal IELT distribution for the males with complaints of PE in the Patrick et al. study [4] was 0.094. For those males in the Giuliano et al. study [5] the GOF was 0.098. According to Kolmogorov and Smirnov the GOF of the Lognormal IELT distribution for the males with no complaints of PE in the Patrick et al. study [4] was 0.061 and for those males in the Giuliano et al. study [5] the GOF was 0.064.

Table 1 Characteristics of four epidemiological stopwatch studies in Europe and USA

	N	Stopwatch	IELT ≤ 1 min	Median	Range
	Total	*N* total *N* (%)	*N* total (%) *N* (%)	*N* total (min)	*N* total (min)
(a)					
Waldinger et al. [9, 10]	965	965 (100.0)	10 (1.2)	5.4	0–54
Patrick et al. [4]	1587	1405 (88.5)	–	–	0–53
Giuliano et al. [5]	1115	1026 (92.0)	–	–	0–50
(b)					
Waldinger et al. [9, 10]	965	965 (100.0)	10 (1.2)	5.4	0–54
Patrick et al. [4]	1587	1405 (88.5)	71 (4.5)	6.3	0–53
Giuliano et al. [5]	1115	1026 (92.0)	12 (1.1)	6.4	0–50

Part (a) shows the data and missing data as published in the original studies of Patrick et al. [4] and Giuliano et al. [5]. In part (b) These missing data are reported by making use of the Probability Density Function of the IELT distribution of both studies, as calculated in Part I [8]

Table 2 Characteristics of men with complaints of PE and characteristics of men with no complaints of PE

	PE males (*N*) *N*	PE males (*N*) IELT ≤ 1 min *N* (%)	PE males (N) Median (min)	PE males (*N*) Mean (min)	PE males (*N*) Range (min)
(a)					
Waldinger et al. [9, 10]	NA	NA	NA	NA	NA
Patrick et al. [4]	190 (13.5)	–	1.8	3.3	0–41
Giuliano et al. [5]	201 (19.6)	–	2.0	3.0	0–25.6
	Non-PE males (*N*) (*N*) *N*	Non-PE males (*N*) IELT ≤ 1 min *N* (%)	Non-PE males (*N*) Median (min)	Non-PE males (*N*) Mean (min)	Non-PE males (*N*) Range (min)
Waldinger et al. [9, 10]	NA	NA	NA	NA	NA
Patrick et al. [4]	1215	–	7.3	10.0	0–53
Giuliano et al. [5]	844	–	10.0	9.2	0–43.7
(b)					
Waldinger et al. [9, 10]	NA	NA	NA	NA	NA
Patrick et al. [4]	190	39 (20)	1.8	3.3	0–41
Giuliano et al. [5]	201	9 (5)	2.0	3.0	0–25.6
	Non-PE males (*N*) (*N*) *N*	Non-PE males (*N*) IELT ≤ 1 min *N* (%)	Non-PE males (*N*) Median (min)	Non-PE males (*N*) Mean (min)	Non-PE males (*N*) Range (min)
Waldinger et al. [9, 10]	NA	NA	NA	NA	NA
Patrick et al. [4]	1215	32 (2.6)	7.3	10.0	0–53
Giuliano et al. [5]	844	3 (0.5)	10.0	9.2	0–43.7

Part (a) shows the characteristics of men with complaints of PE and of men with no PE complaints with missing data of the Patrick et al. [4] and Giuliano et al. [5] studies, as calculated in the current study. In part (b), these missing data are reported by making use of the Probability Density Function of the IELT distribution of both studies, as calculated in the current study I [8]

Comparison of the Lognormal Probability Density Functions of the IELT distributions of both studies show a striking similarity between both cohorts of males with complaints of PE, but also some intriguing differences. Despite a rather similar total number of males with PE complaints (Patrick et al.: $n = 190$; Giuliano et al.: $n = 201$) Patrick et al. [4] have included a less percentage of males (13.5%) with complaints of PE than Giuliano et al. [5] (19.2%) (Part 1: Table 1). In addition, the group of males with complaints of PE of the Patrick et al. [4] study comprises more non-Caucasian males. In the total population, Patrick et al. [4] report 75% Caucasian males and 25% non-Caucasian males. However, according to a clinician diagnosis of PE according to DSM-IV-TR criteria [6], 36% non-Caucasian males have been diagnosed as having complaints of PE versus only 64% Caucasian males. This contrasts the study by Giuliano et al. [5], where after a clinician PE diagnosis 97% Caucasian males have PE. Whether this is due to a difference in clinical diagnosis of PE between clinicians in the USA and Europe, or to a higher percentage of males with complaints of PE in non-Caucasion males remains a matter of speculation.

Tables 1a and 2a show the data as published by the authors of the three large IELT stopwatch studies. The empty boxes in Table 1a and Table 2a represent the data that have not been reported by the Patrick et al. [4] and Giuliano et al. [5] studies. Tables 1b and 2b provide these missing data as calculated in the current study by application of the Probability Density Function formulas (see Part 1 [8]).

In the Patrick et al. study [4] it is reported that of the 1587 men, 1405 males used a stopwatch for IELT measurement, and only 190 men (13.5%) were diagnosed as having PE according to the diagnosis of a clinician on the basis of DSM-IV-TR criteria [6]. Importantly, according to their report, men with an IELT up to 20 min were diagnosed as having PE [4] (Table 1a).

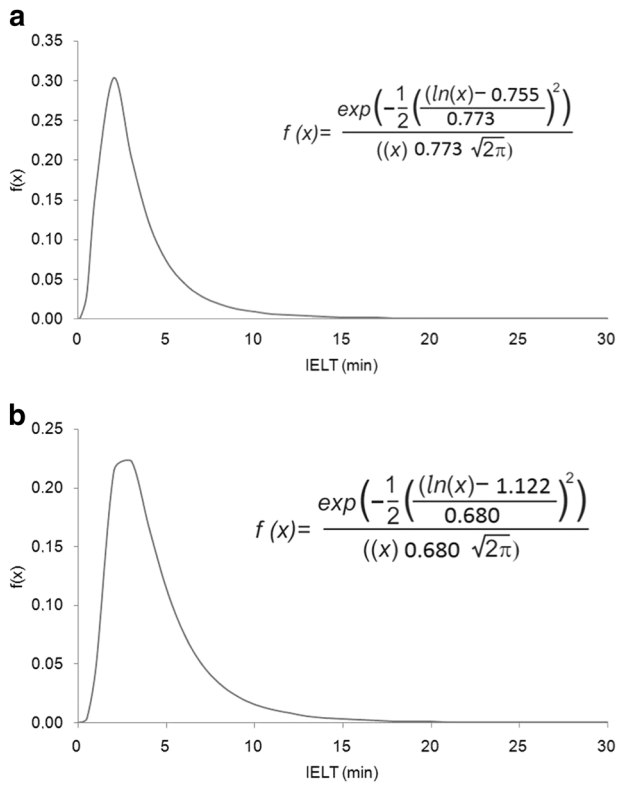

Fig. 1 **a** IELT Probability Density Function of males with complaints of PE. Lognormal distribution with associated formula of the stopwatch-mediated IELT distribution of men with complaints of PE in the USA (The Patrick et al. study) [4]. **b** IELT Probability Density Function of men with complaints of PE. Lognormal distribution with associated formula of the stopwatch-mediated IELT distribution of men with complaints of PE in Europe (France, Italy, Germany, United Kingdom and Poland) (The Giuliano et al. study) [5]

In the Giuliano et al. study [5] it is reported that of 1115 men, 1026 males used a stopwatch for IELT measurement, and only 201 men (19.6%) had PE according to a clinician diagnosis and use of a questionnaire. Importantly, also according to their report men with an IELT up to 20 min were diagnosed as having PE [9] (Table 1a).

Table 2a shows that of the 190 men with complaints of PE in the Patrick et al. study [4], the median IELT was 1.8 min, the mean IELT 3.3 min. Table 2a shows that in their study 39 men (20%) of the men with complaints of PE measured an IELT of less than 1 min.

Table 2a also shows that of the 201 men with complaints of PE in the Giuliano et al. study [5], the median IELT was 2.0 min and the mean IELT 3.0 min. Table 2a shows that in their study nine men (5%) of the men with complaints of PE measured an IELT of less than 1 min.

After applying the mathematical formula of the IELT distributions of the males with complaints of PE, the AUC of the IELT distribution of the males with complaints of PE and the AUC of the general male population were calculated. Based on the context, e.g. the 1 min cut-off point of the IELT has been a 90% cut-off point of the IELT in Dutch Caucasian male with Lifelong PE [11], we have set the significance level at $p = 0.10$ [15, 16].

It was found that at the cut-off point at which the AUC is equal to 10% ($p = 0.10$) the IELT was 1.5 min, indicating that after an IELT of 1.5 min the IELT distribution of males with complaints of PE can no longer be distinguished from the IELT distribution of males in the general population.

Discussion

In the current study, the IELT distributions of the PE men and non-PE men in the studies of Patrick et al. [4] and Giuliano et al. [5] have been mathematically transformed in order to get more mathematical information of the IELT distribution of men with complaints of PE as diagnosed by a clinician judgement on the basis of the DSM-IV-TR definition of PE. By application of the mathematical formulas of the IELT distributions of males with complaints of PE and non-PE males we investigated whether the mathematical IELT distribution of males with complaints of PE differs from the mathematical IELT distribution of the general male population. By calculating the overlap between the mathematical IELT distribution of the males with complaints of PE with the mathematical IELT distribution of the general male population, it was found that both mathematical IELT populations are different in the overlap area between 1 s and 1.5 min. However, as soon as the IELT becomes more than 1.5 min, there is no difference anymore in the mathematical IELT distribution of men with complaints of PE and the mathematical IELT distribution of the general male population. In other words, until 1.5 min the males with complaints of PE differ significantly from the general male population with regard to their IELT values ($p < 0.10$). However, at higher IELT values above 1.5 min, males with complaints of PE cannot anymore be distinguished from the general male population with regard to their IELT values. Therefore a man who ejaculates after, for example, 2 min and has complaints of PE, cannot anymore be distinguished from the general male population based on the IELT. In 2016, Janssen and Waldinger [7] have found that the IELT distribution of Lifelong PE is a Gumbel Max Distribution, and therefore mathematically different from the Lognormal IELT distribution in the general male population. The current study shows that men with complaints of PE also have a Lognormal IELT distribution and therefore are mathematically not different from the IELT distribution in the general male population, at least after IELT values of more than 1.5 min. But it also implies that after 1.5 min the IELT distribution of men with complaints of PE becomes mathematically different from the IELT distribution of men with Lifelong PE.

In 2006, Waldinger and Schweitzer [17–19] have proposed to denote men with complaints of PE and with normal IELT durations with the term Subjective PE. Two random epidemiological stopwatch-mediated IELT studies in five countries have shown that the normal (median) IELT is between 5 and 6 min [9, 10]. In other words, the IELT in Subjective PE is on average more or less than 5–6 min [1, 2, 9, 10]. The findings of the current study imply that males with Subjective PE have the same Lognormal IELT distribution as males in the general population, as has been found in the Netherlands, Germany, United Kingdom, France, Spain, Italy, Poland, Turkey and the USA by the studies of Waldinger et al. [9, 10], Patrick et al. [4] and Giuliano et al. [5], at least after an IELT of 1.5 min. These findings confirm our initial hypothesis. It is of note that the studies of Patrick et al. [4] and Giuliano et al. [5] did not report whether the males with an IELT of less than 1 min had Lifelong PE or Acquired PE. Therefore it remains unknown whether the IELT area between 1 s and 1.5 min belongs to Lifelong PE or to Subjective PE in their studies. However, based on the IELT distribution study of Waldinger et al. [11] in a consecutive cohort of men with Lifelong PE, it may be assumed that the IELT area between 1 s and 1.5 min belongs to Lifelong PE. Consequently, the current study may have implications for the IELT cut-off point of Lifelong PE. As was already noted in 1998 in the original study of Waldinger et al. [11] it was found that a minority of men with Lifelong PE had IELTs of 1 to 1.5 min. Based on the findings of the current study, it may be argued that Subjective PE starts after an IELT of 1.5 min. This finding of males with normal IELT values (but with complaints of PE) is mirrored in the rather sudden rise of number of men with higher IELT values of around 2 min, as is shown by Waldinger et al. [9, 10] in the original IELT distribution of two random samples of the general male population in five counties. Therefore, it may be argued that the current ISSM definition of Lifelong PE [20] and the current DSM-5 [21] definition of PE are not precisely accurate and ought to be changed. Indeed, based on the current mathematical study of four stopwatch-mediated IELT distributions of the general male populations in the USA and Europe, and compared with the IELT distribution of Dutch Caucasian males with Lifelong PE, it would be more accurate to suggest that the cutoff point of the IELT of Lifelong PE is 1.5 min instead of 1 min. This finding is in line with and confirms previous suggestions by Waldinger [1, 3] and the ISSM [20] that the cut-off point of 1 min for Lifelong PE should be handled in a flexible and not dogmatic way. Indeed, the 1 min cut-off point of the IELT has been a 90% cut-off point of the IELT in Dutch Caucasian males with Lifelong PE, according to the study of Waldinger et al. as published in 1998 [11]. A 100% cut-off point of the IELT in their study would be more in line with the current finding of 1.5 min. In addition, the current study also provides more evidence that Subjective PE starts after an IELT of 1.5 min and encompasses all higher IELT values, at least when men complain about PE. In addition, the current study supports pure mathematically our view and hypothesis that Lifelong PE and Subjective PE are two separate disorder entities. It also shows that the disputable dogmatic view of the German Bundesinstitut fur Arzneimittel und Medizinprodukte (BfArM), associated with the European Medicine Agency (EMA) is not in line with current research of PE [1, 2]. Indeed, by strictly adhering to the DSM-5 [21] definition of PE, that erroneously states that not only men with Lifelong PE but also men with Aquired PE ejaculate within 1 min, the BfArM endangers and impedes the development of new drugs to be registered for the treatment of Acquired PE and Subjective PE for the next two decades [1, 2]. This alarming situation has recently been highlighted by Waldinger and Schweitzer [1, 2]. It should therefore be emphasized that a serious limitation of the DSM-5 [21] definition of PE is that it does not mention that men with Acquired PE ejaculate within 3 min as was defined by the ISSM [20] and that it does not mention the existence of a third PE subtype as stated in the ICD-11 MMS [22], which resembles Subjective PE [1, 2]. Obviously, it is of pivotal importance for men with PE that for official registration of new drugs for the treatment of PE, being either on-demand oral or local anaesthetics, the BfArM in Germany and perhaps also other drug registration authorities, associated with the EMA, who share the same rather rigid opinion as the BfArM, will accept a more flexible attitude towards the criteria of PE, which is more in line with current evidence-based research and up-to-date factual knowledge of the three PE subtypes.

Conclusion

In the current study we have shown that there is hard mathematical and statistical evidence showing that the IELT distribution of Lifelong PE and the IELT distribution of men with complaints of PE with normal IELT values (e.g., Subjective PE) belong to two independent populations. The current finding of a clear mathematical difference adds to the already known clinical [23, 24] and epidemiological [25, 26] difference in symptomatology and prevalence of Lifelong PE and Subjective PE, respectively. The clear differences imply that pharmacological research of Lifelong PE and Subjective PE require a more subtype-PE-specific method and design of studies, and not a single method and design focused on the characteristics of only Lifelong PE [3, 27, 28], as has recently unfortunately and erroneously been stated by the German BfArM, associated with the EMA [1, 2]. The current study also provides evidence that

Subjective PE starts after an IELT of 1.5 min and encompasses all higher IELT values, at least in men complaining of PE. Moreover, the findings of the current study may also imply that the current cut-off point of the IELT in Lifelong PE is 1.5 min instead of 1 min, as has previously been stated by the ISSM [20] and DSM-5 [21].

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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