Ejaculatory dysfunction—the evolution of a new understanding

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Abstract: As long as man has breathed, his fascination, pursuit and quest for the perfect sexual experience have remained one of his principal raisons d'être. After thousands of years, millions of words and pictures, and billions of attempts, he still often finds the goal largely unobtainable. Until recently, our understanding of premature ejaculation (PE) was an eclectic mix and homogenization of ancient historical and culturally diverse influences. However, recent basic and clinical research has resulted in a new understanding and a paradigm shift in the way we classify, define, evaluate, diagnose and treat PE.

Keywords: Premature ejaculation (PE); ejaculatory dysfunction

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In many ancient cultures and times, there were many references to the importance of ejaculation and the art of love and sexuality. The Bible states that semen was intended to be deposited only in vaginas and mainly for the purpose of procreation. Men were told: "Be fruitful, and multiply and replenish the earth" (Genesis 2). The punishment for not obeying God's law was death, as Onan was to discover to his peril. Onan's father, Judah, forced him to marry his brother's widow Tamar, whom he did not love. Onan discovered that during coitus he could not ejaculate into Tamar: "he spilled it (semen) on the ground, and the thing which he did displeased the Lord: wherefore He slew him" (Genesis 38).

The Indian god Shiva, who has the power to destroy and create, is often represented with an erect phallus, a symbol of power and fertility. Because Shiva always holds back his seed, the "lingam" (penis) remains erect, as a potential creator (1). Semen is considered to be a precious substance in Indian cultures and many myths have been created around it (2). Atharva-ved, one of the ancient Indian religious books mentions that 100 drops of blood are required to make one drop of semen. Loss of semen was considered then (and still is) as a loss of strength. Male weakness caused by a loss of semen is called "mardana-kamzori" (2); this and premature ejaculation (PE) is collectively known as "Dhat syndrome" (3).

The *Kama Sutra* was written between the first and fourth centuries AD by Mallanaga, a bachelor belonging to the

Vatsyayana sect. It is best described as the lifestyle book of its era which was devoted to personal discipline and offered a range of knowledge that the reader may acquire, to find (and keep) a partner. It gave suggestions on many subjects, from how to freshen the breath by chewing betel leaves to a range of sexual positions that "seems often to be addressed to a contortionist" (4). Although initially published in Britain in 1876, it was considered by Victorian England to be far too lewd and was not officially available until 1963.

Part two of the *Kama Sutra* deals exclusively with sexual intercourse and considers different lengths of time to ejaculation as having various merits. The author believed that "The first time of union the passion of the man is intense, but on subsequent union the reverse of this is true". He observed that, "if a male be long-timed, the female loves him the more, but if he be short timed, she is dissatisfied with him". He concludes "that males when engaged in coition, cease of themselves after emission and are satisfied, but it is not so with females". This is a clear reference to the fact that PE causes bother, frustration and relationship friction.

Chinese sexology can be traced back many dynasties. The Tang Dynasty (618–907 AD) was considered to be sexually free, and during this period sex was positively encouraged as the means to good health. Early Taoist philosophers saw frequent and long-lasting sex as promoting balance between the Yin (negative, dark, feminine) and Yang (positive, bright, masculine). Sex was considered the very essence of

nature and harmony. It was also thought that to ejaculate ("chi") made the man weak for the next sexual encounter. Delaying or suppressing ejaculation was felt to be beneficial, and a disciplined approach to delaying ejaculation became popular. In the Ming Dynasty [1368–1644], attitudes to sex became more restricted, and by the Qing Dynasty [1644–1911], sexuality was repressed and regulated (5).

In sixteenth century Tunisia, Sheikh Nefzawi, adviser to the Grand Vizier of Tunis, wrote a book on the art of love was called *The Perfumed Garden*, the Islamic version of the *Kama Sutra*. He makes specific reference to PE, but offers no remedy for the problem. "When the mutual operation is performed, a lively combat ensues between the two actors who frolic and kiss and intertwine. Man in the pride of his strength, works like a pestle, and the woman, with lascivious undulations, comes artfully to his aid. Soon all too soon the ejaculation comes!"

Erotic life flourished at all levels of society in ancient Egypt (6). Life, the afterlife, fertility and creation are important parts of Egyptian history, and representations of such can be seen on many temple carvings and paintings. Of particular interest were the remedies that the ancient Egyptians considered useful for various sexual ailments and problems. The lotus flower was an important icon in ancient Egypt (7). Magical properties have been associated with the lotus flower since it arose at the beginning of time from the waters of Nun (the original waters) (1). It was immortalized in modern times when lotus and corn flowers were discovered in the coffin of Tut-Ankh-Amon. At the first ray of the sun, the lotus flower opens up and releases a hyacinth like scent. When an Egyptian buried his nose in a lotus flower and kept it there for a while, the effect on him may have been considerable, and the scent may have been sufficient to achieve an alteration in consciousness (8). This may have had the effect of reducing anxiety and possibly delaying ejaculation, although there is no specific mention of PE.

The evolution of the current understanding (and treatment) of PE

In 1887 Gross described what is presumably the first case of rapid ejaculation in the medical literature (9). A report of the German psychiatrist Krafft-Ebing followed in 1901 and referred to an abnormally fast ejaculation but did not yet use the word "praecox" or "premature" (10). In 1917, Karl Abraham described rapid ejaculation, which he called ejaculatio praecox (11).

During the 20th century our understanding of PE evolved

through several distinct periods. Between 1917 and 1950 the consensus was that PE was a neurosis and psychosomatic disorder linked to unconscious conflicts, and was best treated with classical psychoanalysis (11). In 1943 Bernard Schapiro, a German endocrinologist, argued that PE was a psychosomatic disturbance caused by a combination of a overanxious personality and "an inferior ejaculatory apparatus as a point of least resistance for emotional pressure" (12). Schapiro described two types of PE: type B (the sexually hypertonic or hypererotic type) representing a continuously-present tendency to ejaculate rapidly from the first act of intercourse, and type A (the hypotonic type) leading to erectile dysfunction.

During the next 40 years [1950-1990] most health care professionals religiously adhered to Masters and Johnson's hypothesis that PE was largely learned behaviour and was due to episodes of initial rapid intercourse leading to habituation, persistent "failure" and the creation of performance anxiety (13). Several authors suggested that high levels of anxiety and excessive and controlling concerns about sexual performance and potential sexual failure might distract a man from monitoring his level of arousal and recognizing the prodromal sensations that precede ejaculatory inevitability has been suggested as a possible cause of premature ejaculation by several authors (14-17). However, the causal link between anxiety and premature ejaculation is speculative, is not evidence-based and is in fact contrary to empirical evidence from other researchers. Strassberg et al. failed to demonstrate any difference in sexual anxiety between a control group of men with normal ejaculatory control and men with premature ejaculation (18).

During this period, it was thought that a small number of cases of PE were due to a range of urological disorders including hyperesthesia of the glans penis, a short frenulum of the foreskin or changes in the posterior urethra. Treatment for this subset of sufferers included anaesthetizing ointment, incision of the frenulum, application of solutions of silver nitrate, or total destruction of the prostatic urethral verumontanum by electro-cautery. Although the behaviour therapy treatment model was the treatment paradigm, towards the end of this period an increasing number of publications on treatment with psychoactive drugs, such as off-label clomipramine, appeared in the literature (19).

In the years 1990–2005, attention was directed towards the development of an understanding of the pathogenesis of lifelong PE. Waldinger *et al.* ignited the field of sexual medicine when he postulated that time to ejaculate was a biological variable and that lifelong

PE was a neurobiologically and genetically-determined dysfunction (20). He suggested that lifelong PE was related to a diminished central serotonergic neurotransmission and activation or inhibition of specific 5-HT receptors. This position was supported by the outcome data of a number of animal and psychopharmacological treatment studies on PE (21). The notion that PE may have a genetic basis was, however, not new and was initially suggested in 1943 by Bernard Shapiro who noticed that men with PE seemed to have family members with similar ejaculatory complaints (12). Recent studies suggest that men with lifelong PE have a 91% risk of having a first-generation relative with PE suggesting familiar occurrence of PE (22).

In the last 10 years [2005-2015] DNA research in men with lifelong PE and male twin genetic research has supported this genetic hypothesis by providing evidence of genetic polymorphisms of the central serotonergic and dopaminergic system, which is associated with the duration of the IELT (23,24). During this period an increasing number of publications have reported the pharmacological treatment of PE with a variety of different medications which act either centrally or locally to retard the neuropsychological control of ejaculation and subsequent orgasm. The introduction of SSRIs in the early 1990s revolutionised the treatment of PE (21). Multiple wellcontrolled evidence-based studies have demonstrated the efficacy and safety of daily or on-demand administration of SSRIs in delaying ejaculation, confirming their role as firstline agents for the treatment of lifelong and acquired PE (25-27). The PE treatment paradigm, previously limited to behavioural psychotherapy, progressively expanded to include drug treatment (13,28).

The pharmaceutical industry finally developed an interest in the identification of potential therapeutic targets and the development of PE pharmacotherapy. Dapoxetine, a novel rapid acting and short half-life SSRI, originally developed by Eli Lilly and company as an antidepressant, was subsequently sold to Johnson & Johnson in December 2003 and developed by the ALZA Corporation, a division of Johnson & Johnson, as the first oral on-demand treatment for PE. In RCTs, dapoxetine 30 or 60 mg taken 1-2 hr before intercourse is more effective than placebo from the first dose, resulting in a 2.5- and 3.0-fold increases in IELT, increased ejaculatory control, decreased distress, and increased satisfaction (29,30). Dapoxetine was comparably effective both in men with lifelong and acquired PE (31) and was similarly effective and well tolerated in men with PE and co-morbid ED treated with phosphodiesterase type

5 inhibitor drugs (32). Dapoxetine has received approval for the treatment of PE in over 50 countries worldwide. Dapoxetine has not received marketing approval by the US Food and Drug Administration (FDA).

Defining PE

Research into the epidemiology and treatment of PE is heavily dependent on how PE is defined. The medical literature contains several univariate and multivariate operational definitions of PE (13,33-40). Each of these definitions characterise men with PE using all or most of the accepted dimensions of this condition: ejaculatory latency, perceived ability to control ejaculation, and negative psychological consequences of PE including reduced sexual satisfaction, personal distress, partner distress and interpersonal or relationship distress. The first official definition of PE was proposed in 1980 by the American Psychiatric Association (APA) in the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) (41). This definition was progressively revised as the DSM-III-R, DSM-IV and finally DSM-IV-TR definitions to include the "shortly after penetration" as a ejaculatory latency criteria, "before the person wishes it" as a control criteria and "causes marked distress or interpersonal difficulty" as a criteria for the negative psychological consequences of PE (33,42,43).

The DSM-III-R, DSM-IV and finally DSM-IV-TR definitions of PE are all authority-based i.e., expert opinion without explicit critical appraisal, rather than evidencebased, and have no support from controlled clinical and/ or epidemiological studies (44). These DSM definitions are primarily conceptual in nature, contain words such as "persistent", "recurrent", "minimal" and "shortly after" which are both vague in terms of operational specificity and multi-interpretable, and rely on the subjective interpretation of these concepts by the clinician (45-47). Whilst the World Health Organization's International Classification of Diseases (ICD-10) of 1993 definition specifies an IELT cut-off of 15 seconds, the DSM definitions fail to provide any cut-off points (34). The absence of a clear IELT cutoff point in the DSM definitions has resulted in the use of a broad range of latencies for the diagnosis of PE in clinical trials ranging from 1-7 minutes (18,48-55). These ejaculation latencies cut-off points were subjectively chosen by the various authors and were not based on objective measurements of ejaculation latency in men with PE. The failure of DSM definitions to specify an IELT cut-off point means that a patient in the control group of one study may very well be in the PE group of a second study, making comparison of studies difficult and generalization of their data to the general PE population impossible.

Although there have been several large evidence-based observational studies, many were methodologically flawed due to a failure to adequately define their study population, and report a prevalence in excess of that suggested by community based normative stopwatch IELT studies (56-58). The methodology of many of these studies is polarized towards patient reported outcome (PRO) measures of control, satisfaction and distress in men diagnosed with PE using the American Psychiatric Association (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) definition despite some subjects having IELTs as high as 28 minutes (43). Conclusions regarding the epidemiology of PE and the relationship between PRO measures and IELT based on data from studies with inadequately defined and selected trial groups must be regarded with some caution and cannot be reliably generalized to subjects with this condition.

This lack of an evidence based definition and general agreement as to what constitutes PE has hampered clinical research into the etiology and management of this condition, the development of PRO measures to diagnose and assess treatment intervention strategies and is a likely obstacle for regulatory agencies to interpret and assess data from clinical trials of PE investigational drugs (47). Evidence-based definitions seek to limit errors of diagnosis and thereby increase the likelihood that existing and newly developed therapeutic strategies are truly effective in carefully selected dysfunctional populations (59). In addition, a multivariate definition containing several diagnostic criteria will decrease diagnostic errors. In the study of PE, rapidity of ejaculation, perceived ejaculatory self-efficacy or control, and negative personal and interpersonal consequences (e.g., distress) represent diagnostic criteria that require operationalization. Operationalization is the process of defining a construct or variable by the development of a measure, procedure, or operation, for identification of instances of that construct or variable. Operationalization and the careful determination of cut-offs for each variable will minimize but never completely eliminate inclusion (false positive) or exclusion errors (false negative) of PE classification of those who have PE vs. those who do not.

Multivariate evidence-based definitions serve to broaden the focus of clinicians and investigators from single diagnostic criteria such as IELT alone by inclusion of other important subjective variables such as perceived control and distress/bother regarding ejaculatory latency. A multivariate definition of PE provides the clinician a more discriminating diagnostic tool. The first contemporary multivariate evidence-based definition of lifelong PE was developed in 2008 by a panel of international experts (60) and subsequently revised in 2013 into a unified definition with the inclusion of acquired PE (61). It defines PE as "a male sexual dysfunction characterized by (i) ejaculation that always or nearly always occurs prior to or within about 1 minute of vaginal penetration from the first sexual experience (lifelong PE) or a clinically significant and bothersome reduction in latency time, often to about 3 minutes or less (acquired PE); (ii) the inability to delay ejaculation on all or nearly all vaginal penetrations; and (iii) negative personal consequences, such as distress, bother, frustration, and/or the avoidance of sexual intimacy." This definition is limited to heterosexual men engaging in vaginal intercourse and forms the basis of the current office management of PE and the foundation of PE observational, intervention and preference trials.

Based upon the same data that supported the ISSM definition of lifelong PE, the recently published DSM-5 definition of PE (62) now includes an objective ejaculatory latency criterion. DSM-5 defines PE as "...a persistent or recurrent pattern of ejaculation occurring during partnered sexual activity within approximately 1 minute following vaginal penetration and before the individual wishes it. This symptom must have been present for at least 6 months and must be experienced on almost all or all (approximately 75%-100%) occasions of sexual activity. It causes clinically significant distress in the individual." (62). The DSM-5 definition of PE requires clinicians to specify PE as either lifelong or acquired, and as generalized or situational. In addition, the DSM-5 definition of PE distinguishes between mild PE (ejaculation occurring within approximately 30 seconds to 1 minute of vaginal penetration), moderate PE (ejaculation occurring within approximately 15–30 seconds of vaginal penetration) and severe PE (ejaculation occurring prior to sexual activity, at the start of sexual activity, or within approximately 15 seconds of vaginal penetration).

Interested parties including industry observers have, over the past 20 years, witnessed an evolution in our understanding of PE from the initial premise that PE was a psychosexual disorder to a new understanding that some men are born with a genetic propensity to ejaculate rapidly. In parallel with this new understanding, the way we classify, define, evaluate, diagnose and treat PE has undergone a paradigm change. This special focused edition of *Translational Andrology and Urology* explores the

conundrum of PE and is doing so attempts to demystify the epidemiology, pathogenesis and etiology, dimensions, diagnosis and management of this common sexual complaint.

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Footnote

Conflicts of Interest: Dr. Mcmahon is a consultant, investigator and speaker for Johnson & Johnson, Janssen Cilag, Menarini, Ixchelsis, Absorption Pharmaceuticals, Neurohealing and Plethora.

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