# EPIDEMIOLOGY

# Premature Ejaculation Among Italian Men: Prevalence and Clinical Correlates From an Observational, Non-Interventional, Cross-Sectional, Epidemiological Study (IPER)

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**ORIGINAL RESEARCH** 

Paolo Verze, MD, PhD,<sup>1</sup> Davide Arcaniolo, MD, PhD,<sup>2</sup> Alessandro Palmieri, MD,<sup>1</sup> Tommaso Cai, MD,<sup>3</sup> Roberto La Rocca, MD,<sup>1</sup> Marco Franco, MD,<sup>1</sup> Luca Venturino, MD,<sup>1</sup> Marco De Sio, MD, PhD,<sup>2</sup> and Vincenzo Mirone, MD<sup>1</sup>

## ABSTRACT

**Introduction:** There is a great variability in the prevalence of premature ejaculation (PE) worldwide and only few data are available about the Italian population.

Aim: To determine the prevalence of PE in the adult male population in Italy.

**Methods:** Adult men 18 to 80 years old who were sexually active were randomly sampled from patient lists of general practitioners in Italy and were included in this observational, non-interventional, cross-sectional epidemiologic study from January to July 2015.

Main Outcome Measures: Subjects were asked to complete general questionnaires on anthropometric data, lifestyle, education, occupation, economic conditions, general health status, comorbidities, and sexual habits: the Premature Ejaculation Diagnostic Tool (PEDT), the 5-item International Index of Erectile Function, and the Sexual Quality of Life Questionnaire—Male.

**Results:** 1,104 subjects were recruited. Mean age was 45.6 years. Mean prevalence of PE based on PEDT score ( $\geq$ 11) was 18.5%, and 12.4% self-reported an intravaginal ejaculatory latency time shorter than 1 minute. Prevalence of PE proportionally increased with age. 64.6% of patients presented lifelong PE vs 35.4% of patients who reported acquired PE. Estimated prevalence of coexisting PE and erectile dysfunction was 7.0%. Furthermore, overall quality of sexual life was significantly worse in men with PE (P = .006). Enrolled men reported an overall rate of sexual problems in their partners of approximately 30%. 31.3% of patients with PE did not seek help for their dysfunction. No significant differences were noted between patients with and without PE for body mass index, alcohol consumption, smoking habits, physical activity, education, economic conditions, and marital status.

**Conclusions:** PE has a high prevalence in the Italian male population, increases with age, and heavily affects quality of life in patients and their partners. Encouraging data exist concerning the percentage of patients seeking help for their condition. Verze P, Arcaniolo D, Palmieri A, et al. Premature Ejaculation Among Italian Men: Prevalence and Clinical Correlates From an Observational, Non-Interventional, Cross-Sectional, Epidemiological Study (IPER). Sex Med 2018;6:193–202.

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Key Words: Premature Ejaculation; Epidemiology; Premature Ejaculation Diagnostic Tool; Intravaginal Ejaculatory Latency Time; Dapoxetine

## INTRODUCTION

For many years there was no universally accepted definition of premature ejaculation (PE). The International Society for Sexual Medicine (ISSM) developed an evidence-based definition of lifelong PE and secondary  $PE^1$  and to date these have been widely accepted within the scientific community.

According to the ISSM committee, lifelong (primary) PE is defined as (i) ejaculation that always or nearly always occurs

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<sup>&</sup>lt;sup>1</sup>Department of Neurosciences, Sciences of Reproduction and Odontostomatology, Urology Unit, University of Naples "Federico II," Naples, Italy;

<sup>&</sup>lt;sup>2</sup>Department of Woman, Child and General and Specialized Surgery, Urology Unit, University of Campania "Luigi Vanvitelli," Naples, Italy;

<sup>&</sup>lt;sup>3</sup>Department of Urology, Santa Chiara Hospital, Trento, Italy

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 Table 1. Prevalence data from international epidemiologic studies on PE

|   | Evaluated for PE | Sample method     | Prevalence, % |
|---|------------------|-------------------|---------------|
| Park et al, <sup>13</sup> 2010 (South Korea)          | 2,037            | Population sample | 6.7           |
| Stulhofer and Bajic, <sup>14</sup> 2006 (Croatia)     | 601              | Population sample | 9.5           |
| Solstad and Hertoft, <sup>15</sup> 1993 (Denmark)     | 100              | Population sample | 13.0          |
| Dunn et al, <sup>16</sup> 1998 (UK)                   | 617              | GP list           | 14.3          |
| Basile et al, <sup>17</sup> 2005 (Italy)              | 12,558           | Campaign          | 21.2          |
| Laumann et al, <sup>18</sup> 2005 (GSSAB)             | 11,205           | CATI              | 22.5          |
| Porst et al, <sup>12</sup> 2007 (USA, Denmark, Italy) | 12,133           | Web sample        | 22.7          |
| Nolazco et al, <sup>19</sup> 2004 (Argentina)         | 2,456            | Campaign          | 28.3          |
| Laumann et al, <sup>20</sup> 1999 (USA)               | 1,243            | Population sample | 30.3          |
| Read et al, <sup>21</sup> 1997 (UK)                   | 72               | GP waiting room   | 31.0          |
| Lau et al, <sup>22</sup> 2005 (Hong Kong)             | 1,571            | CATI              | 36.9          |
| Tang and Khoo, <sup>23</sup> 2011 (MAL)               | 207              | GP waiting room   | 40.6          |

CATI = computer-assisted telephone interviewing; GP = general practitioner; GSSAB = Global Study of Sexual Attitudes and Behaviors; PE = premature ejaculation.

before or within approximately 1 minute of vaginal penetration from the 1st sexual encounter; (ii) the inability to delay ejaculation in all, or nearly all, vaginal penetrations; and (iii) negative personal consequences such as distress, bother, frustration, and/ or the avoidance of sexual intimacy altogether. Conversely, acquired (secondary) PE is characterized by onset during a man's lifetime, whereby a man with previously normal ejaculatory performance experiences ejaculation occurring within approximately 3 minutes after vaginal penetration. Such definitions are limited to men engaging in vaginal intercourse but probably could be extended to oral and anal intercourse, including intercourse between homosexuals, although the evidence basis at this time is not sufficient to define its meaning within these contexts.<sup>1</sup>

Diagnosis of PE is based mainly on medical and sexual history. Patient-reported outcomes such as the Premature Ejaculation Diagnostic Tool (PEDT) have the potential to identify men with PE.<sup>2</sup> Routine laboratory or neurophysiologic tests are not recommended but can be useful when specific findings arise from the medical history or physical examination.<sup>3</sup>

Etiologic factors associated with PE are not completely understood and can be organic (glans hypersensitivity, prostatitis, neurologic diseases, thyroid dysfunction) and/or psychogenic, although a genetic predisposition has been hypothesized.<sup>4–8</sup>

PE can have a great impact on the quality of sexual life of patients and their partners,  $^{9-11}$  and when strictly associated with erectile dysfunction (ED), the latter is at least 3 times more frequent in patients with PE who, as a result, have depression and anxiety.<sup>12</sup>

Many epidemiologic studies have sought to measure the prevalence of PE in territorial male populations, resulting in a wide variability of study results (Table 1).<sup>13–23</sup> This incongruence can be explained by the different sampling methods and/or the non-consensual definition of PE used, which, as stated

earlier, can vary. In general, population-based studies show a mean PE prevalence that is lower compared with other kinds of studies. For PE, only a few studies of this kind have been performed worldwide. Although epidemiologic data are not homogeneous or consistent, PE often has been considered the most frequent or common male sexual dysfunction, with an estimated prevalence of 20% to 30% in the general population.<sup>4</sup> However, most of these studies used the *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition* (DSM-IV) definition and the ISSM committee stated that, when the ISSM definition is applied, the prevalence of lifelong PE most likely does not exceed 4% of the general population (level of evidence = 3b).<sup>3</sup> Few data are available for the Italian population.<sup>17</sup>

The primary aim of this study was to determine the prevalence of PE in the adult male population of Italy through the use of validated tools. Secondary objectives were (i) to evaluate the prevalence of ED associated with PE using a validated questionnaire (International Index of Erectile Function [IIEF]); (ii) to determine the impact of PE on a patient's quality of sexual life using the Sexual Quality of Life Questionnaire—Male (SQoL-M); (iii) to evaluate patients' perception of their partners' sexual dysfunctions; and (iv) to investigate how patients affected by PE confront their problems.



Figure 1. Patients enrolled in the study. GP = general practitioner.

# Table 2. Sociodemographic data according to PE status

| Subjects recruited, N                   |                      |                             | 1,104                            |
|---|----------------------|-----------------------------|----------------------------------|
| Age (v), n (%)                          |                      |                             |                                  |
| <20                                     |                      |                             | 16 (1 5)                         |
| >20-<30                                 |                      |                             | 136 (12.4)                       |
| >30-<40                                 |                      |                             | 174 (15 7)                       |
| >40-<50                                 |                      |                             | 212 (19.2)                       |
| >50-~60                                 |                      |                             | 249 (22 5)                       |
| >60                                     |                      |                             | 317 (28.7)                       |
| <45                                     |                      |                             | 438 (39.6)                       |
| >45                                     |                      |                             | 666 (60.4)                       |
|   |                      |                             |                                  |
|   | PEDT score $\leq$ 11 | PEDT score $\geq$ 11        | P value between                  |
|   | (without PE)         | (with PE)                   | groups (t-test or $\chi^2$ test) |
| Body mass index (kg/cm²)                |                      |                             | .6522                            |
| Subjects, n                             | 641                  | 150                         |                                  |
| Mean                                    | 25.58                | 25.74                       |                                  |
| SD                                      | 3.72                 | 4.81                        |                                  |
| SE                                      | 0.15                 | 0.39                        |                                  |
| Median                                  | 25.06                | 24.87                       |                                  |
| Min-May                                 | 15 84-45 71          | 1790-60.84                  |                                  |
| Smoking habits (cigarettes/d) n (%)     | 17.64 40.71          | 11.50 00.04                 | 5588                             |
| Never                                   | 293 (/150)           | 62 (38 50)                  |                                  |
| ~10                                     | 108 (15 20)          | 2 (30.30)                   |                                  |
| >10                                     | 136 (19.25)          | 36 (22 36)                  |                                  |
| Former smelver                          | 160 (13.20)          | /3 (26 70)                  |                                  |
| Alcohol consumption p (%)               |                      | 45 (20.70)                  | 1/-28                            |
|   | 170 (10 05)          | 22 (17 75)                  | .1420                            |
| Ossasional                              | (20.51) 50           | الد / حال 22<br>103 (ح/ 37) |                                  |
| Desular                                 | 407 (02.42)          |                             |                                  |
|   | 124 (17.71)          | (۲۱.۵۲) در                  | 2022                             |
|   |                      |                             | .2073                            |
| Never                                   |                      |                             |                                  |
|   | IDZ (ZI./IJ          | 50 (18.98)                  |                                  |
| Moderate                                | 225 (31.85)          | 49 (31.01)                  |                                  |
| Intense                                 | // (II.UU)           | II (6.96)                   | 2202                             |
| Stress condition (everyday life), n (%) | ( ( ( ) )            | 0 (5 50)                    | .3307                            |
| Never                                   | 44 (6.24)            | 9 (5.59)                    |                                  |
| Low                                     | 2/9 (39.57)          | 52 (32.29)                  |                                  |
| Moderate                                | 514 (44.55)          | 83 (51.55)                  |                                  |
| Intense                                 | 68 (9.64)            | 17 (10.55)                  | 2072                             |
| Marital status, n (%)                   |                      |                             | .0978                            |
| Never married                           | 257 (36.35)          | 42 (26.25)                  |                                  |
| Married                                 | 398 (56.29)          | 102 (63.75)                 |                                  |
| Divorced                                | 43 (6.08)            | 13 (8.12)                   |                                  |
| Widower                                 | 9 (1.27)             | 3 (1.87)                    |                                  |
| Kind of cohabitation, n (%)             |                      |                             | .0443                            |
| No partner                              | 147 (21.64)          | 33 (21.29)                  |                                  |
| No cohabitation                         | 145 (21.35)          | 20 (12.90)                  |                                  |
| Stable cohabitation                     | 387 (56.99)          | 102 (65.80)                 |                                  |
| Education, n (%)                        |                      |                             | .5670                            |
| No education                            | 1 (0.14)             |                             |                                  |
| Primary                                 | 43 (6.09)            | 12 (7.50)                   |                                  |
| Secondary                               | 178 (25.21)          | 47 (29.37)                  |                                  |
| High                                    | 367 (51.98)          | 72 (45.00)                  |                                  |
| Academic degree                         | 117 (16.57)          | 29 (18.12)                  |                                  |

(continued)

#### Table 2. Continued

|                           | PEDT score $\leq$ 11 (without PE) | PEDT score $\geq 11$ (with PE) | <i>P</i> value between groups (t-test or $\chi^2$ test) |
|---------------------------|-----------------------------------|--------------------------------|---|
| Employment, n (%)         |                                   |                                | .1537   |
| Student                   | 46 (6.54)                         | 8 (5.03)                       |   |
| Job                       | 480 (68.27)                       | 106 (66.66)                    |   |
| House activity            | 2 (0.28)                          | 1 (0.62)                       |   |
| Retired                   | 99 (14.08)                        | 33 (20.75)                     |   |
| No job                    | 76 (10.81)                        | 11 (6.91)                      |   |
| Economic condition, n (%) |                                   |                                | .3177   |
| Insufficient              | 64 (9.10)                         | 11 (6.91)                      |   |
| Quite insufficient        | 180 (25.60)                       | 41 (25.78)                     |   |
| Sufficient                | 432 (61.45)                       | 96 (60.37)                     |   |
| Good                      | 27 (3.84)                         | 11 (6.91)                      |   |

Max = maximum; Min = minimum; PE = premature ejaculation; PEDT = Premature Ejaculation Diagnostic Tool; SE = standard error.

# METHODS

This observational, non-interventional, cross-sectional epidemiologic study (Italian Premature Ejaculation Research [IPER]) was conducted in a cohort of adult men (IPER-M) representative of the overall Italian male population, regardless of sexual orientation.

In Italy, under the national health system, every citizen consults a local general practitioner (GP) for primary care and therefore the entire population can be considered included in the country's GP database. Of all 20 Italian regions, a sample of 4 has been chosen: 1 each for northern and central Italy and 2 for southern Italy. For each region a large city and a small town were selected. The largest metropolitan areas (ie, Milan, Rome, and Naples) were excluded from the sampling because of their complex social fabric and the risk of involving more distinct ethnic groups. 25 GPs from northern Italy, 8 from central Italy, and 14 from southern Italy were involved in the study, with a 3:1:2 ratio, which reflects the ratio of the residential population living in these 3 macro-areas as designated by the Italian Central Institute of Statistics.<sup>24</sup> 47 GPs were selected from a database of 46,000 based on their experience in clinical and epidemiologic studies. Approximately 55,000 citizens, accounting for 1% of the total population, consult these GPs and therefore a random sample of this group can be considered representative of the Italian population.

Subjects were randomly sampled from the patient lists of selected GPs. Randomization of patients was done anonymously with software devised by the study team and subjects were chosen from the entire list of male and female patients provided by each regional GP.

Inclusion criteria consisted of adult men 18 to 80 years old who were sexually active with a hetero- or homosexual orientation and of any ethnicity. Subjects with cognitive or linguistic deficiency who could not complete the questionnaires or who reported no sexual activity at the time of questionnaire completion were excluded. All participants, after signing an informed consent form, received a series of questionnaires to be returned anonymously to their GPs in a sealed envelope that was opened by an independent staff responsible for processing the data. The study was conducted from January to July 2015.

The general questionnaire distributed gathered the following information: anthropometric data, lifestyle (smoking, alcohol, physical activity, exposure to stress), marital status, education, occupation, economic conditions, general health status, and comorbidities, including non-urologic and non-andrologic comorbidities.

In addition, the IPER-M study population was asked to complete validated self-administered questionnaires: (i) the PEDT for the evaluation of  $PE^{25}$ ; (ii) the IIEF-5 for the evaluation of  $ED^{26}$ ; and (iii) the SQoL-M to determine the impact of PE and ED on male sexual life.<sup>27</sup> The Italian version of all questionnaires was provided and their use was authorized by Pfizer Pharmaceutical Inc (New York, NY, USA).

Based on PEDT score, patients were classified into 2 groups: those affected by PE with a PEDT score of at least 11 (PE+) and those not affected by PE with a PEDT score lower than 11 (PE-). All subsequent sub-analyses were performed using these cutoff scores.<sup>25</sup>

All subjects self-reported their sexual orientation and sexual behavior (frequency of sexual intercourse, ejaculation time, onset of PE [lifelong and acquired)]. Each patient was asked to give anonymous information about his partner including age, education level, health status, and related sexual disorders. Partners' sexual dysfunction was reported and evaluated by the male patients.

The availability of information and resources about PE (doctors, health workers, sources of documentation) was inquired of the patients.

This study did not involve any treatment or invasive diagnostic procedure. In accord with Italian law, the survey was

| · · · ·                                   | -           | ,           |             |             |             |             |
|---|-------------|-------------|-------------|-------------|-------------|-------------|
|   |             | 18—45 y old |             | 46—80 y old |             | 18—80 y old |
| PEDT, n                                   |             | 470         |             | 311         |             | 869         |
| PEDT score $\geq$ 11, %                   |             | 14.9        |             | 33.5        |             | 18.5        |
| IELT $<$ 1 min self-estimated (IPER-M), % |             | 7.6         |             | 17.7        |             | 12.4        |
|   | 18—29 y old | 30—39 y old | 40—49 y old | 50—59 y old | 60—69 y old | 70—80 y old |
| PEDT score $\geq$ 11, %                   | 12          | 12.1        | 20.2        | 18.1        | 26.8        | 18.1        |
| IELT $<$ 1 min self-estimated (IPER-M), % | 5.0         | 6.9         | 9.1         | 11.7        | 11.9        | 21.8        |

**Table 3.** Prevalence of premature ejaculation according to IPER-M study populations

IELT = intravaginal ejaculatory latency time; IPER-M = Italian Premature Ejaculation Research in Men; PEDT = Premature Ejaculation Diagnostic Tool.

conducted in accordance with the Privacy Act and with the Declaration of Helsinki in all aspects that were applicable. Each subject was informed about the purpose of the investigation and was recruited after signing an informed consent.

#### Statistics

Descriptive statistical analysis was applied to the results. The  $\chi^2$  test, Fisher exact test for categorical variables, or Student t-test for continuous variables was performed in specific cases. For all statistical tests, the statistical significance level (*P*) was less than or equal to .05. Data were distributed normally, as demonstrated by asymmetry and kurtosis analysis.

The sample size, set at 1,100 subjects, was selected a priori because it is comparable to that of other country-specific epidemiologic population surveys<sup>13,14</sup> or proportionate with the Italian contribution to international surveys.<sup>12,18</sup>

Data were analyzed using SAS 9.2 (SAS Institute, Cary, NC, USA).

#### RESULTS

2,571 men were sampled and 1,104 (43%) were recruited in the study (Figure 1). Compared with the overall Italian male population, our sample corresponds with 4.8 per 100,000 of the Italian male population of the same age (data from the national census of 2012).

Sociodemographic data according to PE status are presented in Table 2. Mean age was 45.6 years, with 39.6% of the sample younger than 45 years. No significant differences were noted between the PE+ and PE- groups for weight, height, and body mass index, although more subjects in the PE+ group had a mass index (range = 22-25 kg/cm<sup>2</sup>, lower body median = 24.87) and more subjects in the PE- group had a higher body mass index (range = 26-30 kg/cm<sup>2</sup>, median = 25.06). The 2 groups did not differ in alcohol consumption, smoking habits, physical activity, or stress condition in everyday life. No differences were noted between the PE+ and PE- groups for education, employment status, economic class, and marital status. 98% of patients were heterosexual, 1.3% were homosexual, and 0.7% were bisexual.

Mean prevalence of PE in men 18 to 80 years old was 18.5% (Table 3) based on PEDT score ( $\geq$ 11), and 12.4% of men self-reported an intravaginal ejaculatory latency time (IELT) shorter than 1 minute.

With the exception of subjects 50 to 59 and 70 to 80 years old, prevalence of PE proportionally increased with age. For each age class and PEDT score, the subjects' self-estimated IELT showed a similar epidemiologic trend increasing with age when the cutoff value for PE diagnosis was an IELT shorter than 1 minute (Table 3).

64.6% of patients in the PE+ group presented lifelong PE vs 35.4% of patients reporting acquired PE.

Figure 2 shows the ED trend in the IPER-M study population. Results showed that ED was consistently more prevalent in the PE+ group, regardless of age, compared with the PEgroup. Overall estimated prevalence of coexisting PE and ED was 7.0%, which increased with age.

Sexual attitudes are listed in Table 4. The PE+ group reported a significantly lower frequency of sexual intercourse than the PE- population. In fact, 18.4% of the PE+ group engaged in no sexual intercourse at all compared with 11.5% of the PE- group. In addition, 46.5% of the PE- group had intercourse at least once per week vs only 33.3% of the PE+ group. In addition, subjects



**Figure 2.** General population prevalence of erectile dysfunction (5-item International Index of Erectile Dysfunction score  $\leq$  22; dashed black line) compared with erectile dysfunction prevalence in subgroups with (red line with squares) and without (blue line with triangles) premature ejaculation.

 Table 4. Sexual attitudes according to premature ejaculation status

|                          |              |              | P value |
|--------------------------|--------------|--------------|---------|
|                          | FL+, II (70) | FL-, II (70) |         |
| Frequency of intercourse |              |              | <.001   |
| No sexual intercourse    | 64 (18.4)    | 102 (11.5)   |         |
| <1 time/mo               | 57 (16.4)    | 116 (13.1)   |         |
| 2—3 times/mo             | 111 (31.9)   | 256 (28.9)   |         |
| ≥1 time/mo               | 116 (33.3)   | 412 (46.5)   |         |
| Pain during intercourse  |              |              | .021    |
| Never                    | 205 (82.0)   | 660 (88.6)   |         |
| Sometimes                | 38(15.2)     | 76 (10.2)    |         |
| Often                    | б (2.4)      | 9 (1.2)      |         |
| Always                   | 1 (0.4)      | 0 (0.0)      |         |
| Lack of orgasm           |              |              | .006    |
| Never                    | 211 (81.5)   | 631 (83.2)   |         |
| Sometimes                | 27 (10.4)    | 103 (13.6)   |         |
| Often                    | 15 (5.8)     | 16 (2.1)     |         |
| Always                   | 6 (2.3)      | 8 (1.1)      |         |
| No interest in sex       |              |              | .001    |
| Never                    | 197 (62.7)   | 592 (71.2)   |         |
| Sometimes                | 78 (24.8)    | 193 (23.2)   |         |
| Often                    | 24 (7.6)     | 27 (3.2)     |         |
| Always                   | 15 (4.8)     | 19 (2.3)     |         |

$$\label{eq:PER-M} \begin{split} \text{IPER-M} = \text{Italian Premature Ejaculation Research in Men; } \text{PE}- = \text{without} \\ \text{premature ejaculation; } \text{PE}+ = \text{with premature ejaculation.} \end{split}$$

with PE expressed a more frequent lack of sexual interest, lack of orgasm, and pain during intercourse based on the questionnaire response of "often" and "always" compared with the PE- population (lack of sexual interest: PE+ 12.4% vs PE- 5.5%, P = .001; lack of orgasm: PE+ 8.1% vs PE- 3.2%, P = .006; pain during intercourse: PE+ 2.8% vs PE- 1.2%, P = .021). Furthermore, overall quality of sexual life as evaluated by the SQoL-M was significantly worse in the PE+ than in the PE- group (7.34 vs 7.73, P = .006, respectively).

Table 5 lists the partners' sexual dysfunction as reported by the IPER-M study population. Enrolled men reported an overall rate of sexual problems in their partners of approximately 30% based on the answers "sometimes" and "often" for each of the items related to their partners' sexual complaints. The prevalence of partners who reported a lack of interest in sex and delayed or absence of orgasm was significantly higher based on the questionnaire responses of "often" and "always" in the PE+ vs PE- group (lack of interest in sex: 12.0% vs 5.7%, P < .001; delayed orgasm: 11.3% vs 3.1%, P = .001; absent orgasm: 5.9% vs 3.8%, P < .001, respectively). Also, vaginismus was more frequently reported in partners of patients with PE (PE+ 14.3% vs PE- 4.9%, P = .029).

Conversely, the prevalence of pain during intercourse and anxiety during intercourse did not differ between the 2 groups (pain during intercourse: PE+ 7.8% vs PE- 3.1%, P = .08; anxiety: PE+ 8.3% vs PE- 6.0%, P = .39).

The PE+ group less frequently shared sexual problems with their partners compared with the PE- group (25.1% vs 33.0%, P = .016).

Based on the questionnaire response, 31.3% of the PE+ group did not seek help or take any remedial action for their dysfunction. In particular, 56.9% assumed that there was no cure for PE and 49% stated that PE was not a problem for them (Table 6A). Patients who sought help consulted a physician (75%), shared their problems with their partner (40.4%), or tried to resolve the problem by themselves (27.2%). Subjects with PE who underwent only 1 medical consultation preferred to consult their GP (56.3%) and a urologist or andrologist (28.2%), which was the same for patients who requested more than 1

**Table 5.** Partner's sexual dysfunction reported by IPER-M study population

| IPER-M             | PE+, n (%) | PE-, n (%) | $P$ value ( $\chi^2$ test) |
|--------------------|------------|------------|----------------------------|
| No interest in sex |            |            | <.001                      |
| Never              | 87 (58.0)  | 254 (75.6) |                            |
| Sometimes          | 45 (30.0)  | 63 (18.8)  |                            |
| Often              | 18 (12.0)  | 19 (5.7)   |                            |
| Always             | 0          | 0          |                            |
| Lack of orgasm     |            |            | <.001                      |
| Never              | 74 (62.2)  | 197 (83.5) |                            |
| Sometimes          | 38 (31.9)  | 30 (12.7)  |                            |
| Often              | 7 (5.9)    | 9 (3.8)    |                            |
| Always             | 0          | 0          |                            |
| Delayed orgasm     |            |            | .001                       |
| Never              | 56 (57.7)  | 211 (82.1) |                            |
| Sometimes          | 30 (30.9)  | 38 (14.8)  |                            |
| Often              | 11 (11.3)  | 8 (3.1)    |                            |
| Always             | 0          | 0          |                            |
| Pain               |            |            | .080                       |
| Never              | 66 (73.3)  | 190 (83.0) |                            |
| Sometimes          | 17 (18.9)  | 32 (14.0)  |                            |
| Often              | 7 (7.8)    | 7 (3.1)    |                            |
| Always             | 0          | 0          |                            |
| Anxiety            |            |            | .39                        |
| Never              | 37 (61.7)  | 84 (71.8)  |                            |
| Sometimes          | 18 (30.0)  | 26 (22.2)  |                            |
| Often              | 5 (8.3)    | 7 (6.0)    |                            |
| Always             | 0          | 0          |                            |
| Vaginism           |            |            | .0290                      |
| Never              | 33 (67.3)  | 71 (86.6)  |                            |
| Sometimes          | 9 (18.4)   | 7 (8.5)    |                            |
| Often              | 7 (14.3)   | 4 (4.9)    |                            |
| Always             | 0          | 0          |                            |
| Problem sharing    |            |            | .016                       |
| Never              | 111 (58.1) | 240 (46.0) |                            |
| Sometimes          | 32 (16.8)  | 110 (21.1) |                            |
| Often              | 48 (25.1)  | 172 (33.0) |                            |
| Always             | 0          | 0          |                            |

IPER-M = Italian Premature Ejaculation Research in Men; PE- = without premature ejaculation; PE+ = with premature ejaculation.

**Table 6A.** Heterogeneity of reactions in patients with premature ejaculation

| Total sample                | 161 | 100.0% |
|-----------------------------|-----|--------|
| No action                   | 51  | 31.7%  |
| Any action                  | 136 | 84.5%  |
| Both answers                | 31  | 19.3%  |
| No answer                   | 5   | 3.1%   |
| No action                   | 51  | 100.0% |
| lt is not a problem         | 25  | 49.0%  |
| There is no care            | 29  | 56.9%  |
| Multiple answers            | 3   |        |
| No answer                   | 110 |        |
| Only 1 medical consultation | 71  | 100.0% |
| Family doctor               | 40  | 56.3%  |
| Urologist or andrologist    | 20  | 28.2%  |
| Sexologist                  | 9   | 12.7%  |
| Endocrinologist             | 0   | 0.0%   |
| Psychologist                | 2   | 2.8%   |
| Other                       | 0   | 0.0%   |
| Total medical consultations | 150 | 100.0% |
| Family doctor               | 63  | 42.0%  |
| Urologist or andrologist    | 42  | 28.0%  |
| Sexologist                  | 25  | 16.7%  |
| Endocrinologist             | 2   | 1.3%   |
| Psychologist                | 16  | 10.7%  |
| Other                       | 2   | 1.3%   |
| Multiple answers allowed    | 79  | 52.7%  |

consultation (42% and 28%, respectively; Table 6A). Patients affected by PE treated their problem with a condom (43.5%), drugs (29%), natural products (19.4%), or other treatments (8.1%), which was usually based on the advice of their doctor and/or pharmacist (58.1%; Table 6B).

#### DISCUSSION

Data from this observational, non-interventional, crosssectional epidemiologic study examined the prevalence of PE in the adult male population in Italy based on a combination of results from validated questionnaires (PEDT) and self-reported IELTs, rather than through the determination of sexual attitudes of patients with PE and their partners.

To date, the largest study to assess PE prevalence and its associated conditions in the Italian population was performed by Basile Fasolo et al<sup>17</sup> in 2005, which reported an overall PE prevalence of 21.2%; however, at the time, that study lacked the use of validated tools for determining epidemiologic trends of PE.

The results of the present study show an overall PE prevalence that is significantly lower than that reported by the US National Health and Social Life Survey study<sup>20</sup> and the Premature Ejaculation Prevalence and Attitudes (PEPA) study.<sup>12</sup> More importantly, our study shows some other interesting findings. (i) It indicates that self-reported IELTs tend to underestimate PE prevalence compared with the PEDT questionnaire, particularly in younger patients. (ii) There is an increasing linear, parallel

|                          | Sources               |          |         |           |            |
|--------------------------|-----------------------|----------|---------|-----------|------------|
| Products                 | Doctor/<br>Pharmacist | Internet | Media   | Friends   | Total      |
| n (%)                    | 36 (58.1)             | 9 (14.5) | 7(11.3) | 10 (16.1) | 62 (100.0) |
| Pharmaceutical,<br>n (%) | 13 (21.0)             | 3 (4.8)  | 2(3.2)  | 0         | 18 (29.0)  |
| Natural, n (%)           | 5 (8.1)               | 2 (3.2)  | 1(1.6)  | 4(6.5)    | 12(19.4)   |
| Condom, n (%)            | 18 (29.0)             | 3 (4.8)  | 3 (4.8) | 3 (4.8)   | 27 (43.5)  |
| Other                    | 0                     | 1 (1.6)  | 1 (1.6) | 3 (4.8)   | 5 (8.1)    |

trend for PE prevalence and age, which is confirmed from the PEDT score or IELT.

As addressed by previously published studies,<sup>28,29</sup> use of IELT alone is not sufficient to define PE because there is significant overlap between men with and without PE. Patrick et al<sup>30</sup> clearly demonstrated that IELT has a significant direct effect on perceived control over ejaculation, but no significant direct effect on ejaculation-related personal distress or satisfaction with sexual intercourse.

Furthermore, we found that PE prevalence is related to age and this datum contrasts with most previously published series, which found no variations in PE frequency among different age categories<sup>4,12,18,31</sup> or decrease with age.<sup>17</sup> Nevertheless, the PEPA survey showed an increased PE prevalence with age up to 45 to 50 years old; however, beyond this age range no further increase was reported. This result could be explained by the fact that the PEPA study was conducted as an internet survey and perhaps 45to 80-year-old subjects were not fully representative of the general population.<sup>12</sup> Conversely, the present study's sample was specifically selected from the outset to be representative of the entire Italian population across different age groups. It also is worth highlighting that, if the 1st diagnosis of life-long PE is delayed (ie, a 50-year-old man who complains of his problem to his doctor for the very 1st time), his report of PE is classified under that specific (advanced) age range, even if it started at a younger age. However, further studies are needed to confirm these data.

Approximately 65% of our patient series was diagnosed with lifelong PE, which is similar to that reported from previously published data.<sup>32,33</sup>

For ED and PE comorbidity, our study showed a higher frequency of ED in the PE+ than in the PE- group, especially for mild to moderate ED (59.1% vs 32.3%, respectively). These results confirm the hypothesis that the relation between PE and ED is a vicious circle and the 2 conditions are closely linked to each other, as suggested by Jannini et al.<sup>34</sup> In a recent meta-analysis Corona et al<sup>35</sup> showed that the presence of PE was associated with a significant increase in ED risk (odds ratio = 3.68, P < .0001) and that this risk was higher in older patients. They concluded that ED and PE should not be considered separate conditions but should be considered from a multidimensional perspective to confront the problem adequately. Our analysis concludes that men affected by PE present a higher rate of loss of libido, lack of pleasure during ejaculation, and pain during intercourse, which significantly affects their sexual quality of life, which is at least 3 times worse than in subjects without PE. These data show that the clinical impact of the problem seems to be much more relevant than the statistical numeric data. In consequence, patients with PE reported less frequent sexual intercourse and a greater tendency to avoid sex with their partners compared with the PE- population. These results confirm previous findings reporting that men with PE are more likely to report low satisfaction with their sexual relationships, low satisfaction with sex altogether, and, in consequence, less frequent intercourse.  $^{36,37}$ 

Men with PE reported a significantly higher rate of sexual dysfunction with their partners compared with subjects without PE. Although a male partner's report of a female partner's sexual dysfunction is fraught with potential error, this report is consistent with studies conducted in women.<sup>11,38</sup> Hobbs et al<sup>11</sup> reported that 77.7% of women with partners with PE had at least 1 sexual dysfunction when evaluated by a validated questionnaire (Abbreviated Sexual Function Questionnaire), but that prevalence was significantly lower (29.7%) and comparable to our results obtained from men directly asking their female partners whether they experienced a sexual problem during intercourse. All sexual domains are found to be significantly worse in the partners of men with PE.<sup>39</sup>

Although PE determines an impaired quality of life, data from the literature showed a low rate of men seeking medical treatment for their dysfunction. The Global Study of Sexual Attitudes and Behaviors survey showed that 78% of men affected by sexual dysfunction did not seek any professional consultation, whereas men were more likely to consult a clinician for ED rather than for PE.<sup>18</sup> The PEPA study showed that only 9% of men with self-reported PE consulted a doctor.<sup>12</sup> The most frequent reasons for not discussing PE with the physician were embarrassment and the belief that no treatment exists for this condition. In our series we detected a lower rate of patients not seeking help for their problem. This finding could be explained by the fact that several campaigns were carried out in Italy in recent years with the aim of increasing awareness about PE, the need to face the problem, and proposing remedial measures, if not cures. Surprisingly, even if approximately 6 of 10 patients with PE do realize and share their condition with their health practitioner, it is evident that most of them do not resort to the drug dapoxetine, which is the only available on-label therapeutic option, but instead revert to the use of a condom.<sup>40</sup> In our opinion, these data can be explained by the fact that more than half the patients seeking help for their dysfunction consult GPs who are less inclined to follow indications of currently available guidelines or from inappropriate drug adherence, for economic reasons, or difficulty in changing old routines.

There are some limitations in the present study that must be acknowledged. (i) Although the study methodology was aimed at minimizing the challenge of assembling a sampling pool based on the population variables being studied, the standard limitations of an observational cross-sectional study could not be overcome. For instance, the study sample was limited in overall size and this can impair a representation of the entire population. Furthermore, study data cannot be accurately used to analyze patients' attitudes over time. (ii) The use of the PEDT and self-estimated IELT to define presence of PE was not fully representative of the ISSM evidence-based definition. Moreover, the PEDT is actually a patient-reported outcome that uses the outdated DSM-IV definition. (iii) Less than 2% of our patient sample was not heterosexual but was included in the final analysis. (iv) Owing to self-reported outcomes regarding subjects and their partners' sexual dysfunction without the use of validated tools, these data could be biased. In addition, although Pfizer Pharmaceutical provided and authorized the use of Italian versions of all questionnaires, none were validated.

## CONCLUSIONS

The data from this observational, non-interventional, crosssectional, epidemiologic study show a PE prevalence representative of the Italian male population of 18.5% through the use of the PEDT and 12.4% by self-estimated IELT. The estimated prevalence of coexisting PE and ED was found to be 7.0%, which increased with age, although it is acknowledged that future studies are needed to confirm these findings. Overall, PE undoubtedly impairs the quality of sexual life in patient and partner. However, encouraging data exist concerning the percentage of patients seeking help for their condition, although most do not follow existing guidelines when deciding on a therapeutic option.

**Corresponding Author:** Davide Arcaniolo, MD, PhD, Department of Woman, Child and General and Specialized Surgery, Urology Unit, University of Campania "Luigi Vanvitelli," Via Costantinopoli, 104, 80138 Naples, Italy. Tel: +39 081 5666816; Fax: +39 081566 6816; E-mail: davide.arcaniolo@gmail.com

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## STATEMENT OF AUTHORSHIP

#### Category 1

- (a) Conception and Design Vincenzo Mirone
- (b) Acquisition of Data Davide Arcaniolo; Roberto La Rocca; Marco Franco
- (c) Analysis and Interpretation of Data Paolo Verze; Davide Arcaniolo; Alessandro Palmieri; Tommaso Cai

#### Category 2

#### (a) Drafting the Article

Paolo Verze; Davide Arcaniolo; Roberto La Rocca; Marco Franco; Luca Venturino

(b) Revising It for Intellectual Content Paolo Verze; Alessandro Palmieri; Tommaso Cai; Marco De Sio; Vincenzo Mirone

## Category 3

(a) Final Approval of the Completed Article

Paolo Verze; Davide Arcaniolo; Alessandro Palmieri; Tommaso Cai; Roberto La Rocca; Marco Franco; Luca Venturino; Marco De Sio; Vincenzo Mirone

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