

## ORIGINAL ARTICLE

# Prevalence of erectile dysfunction among middle-aged men in a metropolitan area in Germany

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**The comparison of results of previous studies on the prevalence of erectile dysfunction is hampered due to differences in study design and research instruments including definitions used. The aim of the study was to determine the prevalence of erectile dysfunction/erectile disorder (ED) using different definitions. An epidemiological cross-sectional study was conducted between May and November 2002 in Berlin, Germany. A total of 6000 men between 40 and 79 years of age were randomly selected by the Berlin Office of Vital Statistics and were sent a questionnaire by mail. The prevalence of ED was determined using five different methods. A total of 1915 questionnaires were eligible for analysis. The five different definitions yielded age-adjusted ED prevalence rates between 18 and 48%. Age was strongly correlated with all five definitions ( $P < 0.001$ ). These results indicate the need for standardized criteria when conducting future studies on ED and may aid in designing public health and clinical management strategies.**

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## Introduction

Erectile dysfunction is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual function,<sup>1</sup> whereas erectile disorder (ED) is the recurrent inability to achieve or maintain an adequate erection until completion of sexual activity while simultaneously causing distress and interpersonal problems.<sup>2</sup> Despite the fact that investigating erectile dysfunction/ED is difficult due to the nature of the topic, the amount of epidemiological research has increased over the past five decades. However, the prevalence rates found in these studies have varied widely.<sup>3–10</sup> The first epidemiological study of male sexual behavior was published in 1948 by Kinsey *et al.*<sup>11</sup> They recruited a total of 15 781 men up to 80 years of age and found a prevalence of erectile dysfunction ranging from <1% for young men to 80% in the uppermost age

group. The Massachusetts Male Aging Study, a community-based observational study of a random sample of men between 40 and 70 years of age, showed a 52% overall prevalence rate for impotence.<sup>12</sup> The German 'Cologne Male Study' ( $n = 4489$ ) found an overall prevalence of erectile dysfunction of 19%, which increased dramatically with age: while the prevalence in men aged 30–39 years was 2%, it was 53% in men aged 70–79 years.<sup>13</sup> A recent study in Finland ( $n = 3787$ ) reported an overall prevalence of 77% in men between 50 and 75 years of age.<sup>14</sup> In other studies, prevalence rates of erectile dysfunction have ranged from 61% in Belgium, 69% in Italy to about 80% in Japan.<sup>15–18</sup> The variability in various aspects of previous investigations such as ED definitions, questionnaire used, study design, age distribution, study population and sample size make a comparison of ED prevalence rates difficult. Quantitative data on the effect of different definitions of ED on the prevalence are lacking, because precise information on the used definition and questionnaire is often absent. Boer *et al.*<sup>19</sup> quantified the effect of using different questionnaires for ED on the prevalence estimates and conducted a difference of 16.8% between International Index of Erectile Function (IIEF), WHO, KEED and one question.

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In addition, knowing the prevalence of erectile dysfunction does not provide any information about the distress experienced by affected patients; nor does it give any insight into the clinical relevance of the condition.

In a meta-analysis, Simon and Cary<sup>20</sup> observed that previous studies had not taken the DSM-IV criteria into account, which resulted in a lack of prevalence data on ED.

Therefore, the aim of the present study was to determine the prevalence of erectile dysfunction/ED using five different definitions.

## Methods

### Study design and subjects

This epidemiological cross-sectional study, called the Berlin Male Study, was conducted in Berlin, Germany between May and November 2002. The sample was selected as follows: out of all 680 000 Berlin men between the ages of 40 and 79, 16 210 men were selected randomly. This resulted in the following distribution, which was representative (with respect to age) of the general male population in the city: 40–49 years of age,  $n = 5000$  (31%); 50–59 years of age,  $n = 4685$  (29%); 60–69 years of age,  $n = 4606$  (28%); and 70–79 years of age,  $n = 1919$  (12%). From each of these four age groups, 1500 men were selected randomly to guarantee a minimum sample size in each age group. The total sample ( $n = 6000$ ) was then contacted by standard mail. Nonresponders were contacted by standard mail a second time and asked to return the questionnaire. The addresses were provided by the Berlin Office of Vital Statistics. The ethics committee of the Charité University Medical Center, Berlin granted approval for the study, which was conducted according to the stipulation of the German Data Protection Act.

### Research instrument

The developed questionnaire was tested in a pilot phase and modified for improved feasibility, clarity and understandability on a group of 30 male patients above 30 years of age, who had presented with urological conditions. This research instrument consists of six sections: (1) socio-demographics (including nationality, age, marital status, highest level of education, current occupational status), (2) health history (including medical conditions, medications, operations), (3) health status (EuroQol Visual Analog Scale), (4) lifestyle variables, quality of life (SF-12), (5) satisfaction with current state of relationship and (6) sexuality (including: sexual orientation, relationship status, frequency of sexual activity, importance of and satisfaction with sex life, erectile function).

Every section starts with a brief instruction how to answer the questions. The sexuality section additionally begins with the definitions of sexual intercourse, sexual activity (including sexual intercourse, caresses and masturbation) and sexual stimulation (including all stimulating situations with the partner).

The presence of ED was determined using five different definitions. The first three definitions used the erectile function (EF) domain. The EF domain is comprised of a six-item checklist (five items of the IIEF, a standard sexual function questionnaire that includes questions about the ability to achieve and maintain erections to the completion of sexual intercourse and one item about the confidence to achieve and maintain an erection) consistent with NIH guidelines for the definition of erectile dysfunction, concerning erectile function over the past 4 weeks.<sup>1</sup> The EF domain demonstrates favorable statistical properties as a diagnostic tool not only in distinguishing between men *without* erectile dysfunction (EF scores between 26 and 30) and *with* erectile dysfunction (EF scores between 1 and 25), but also in categorizing erectile dysfunction into four levels of severity. An EF score between 25 and 22 indicates 'mild' severity, between 21 and 17 'mild to moderate' severity, and between 16 and 11 'moderate' severity of erectile dysfunction.<sup>21,22</sup> The categorization of the fourth level 'severe' erectile dysfunction is dependent on whether the sexually inactive men are included in the analysis or not. When sexually inactive men *are* included, an EF score of 10–1 leads to a rating of 'severe' erectile dysfunction – and when sexually inactive men are *not included*, a rating of 'severe' erectile dysfunction is reached by an EF score between 10 and 6.<sup>23</sup>

Prevalence rates based on the EF domain were assessed in this study according to the following three definitions:

- Definition 1: includes all men, whether sexually active (over the last 4 weeks) or not, and is thus referred to as ED 'EF all'.
- Definition 2: includes only sexually *active* men (over the last 4 weeks), and is thus referred to as ED 'EF active'.
- Definition 3: includes all sexually *active* men (over the last 4 weeks) as well as those sexually *inactive* men (over the last 4 weeks) who have low confidence in their ability to achieve and/or maintain an erection, and is thus referred to as ED 'EF confidence'. ('Low' summarizes the categories 'moderate', 'low' and 'very low' confidence). Men were classified as sexually *inactive* if they reported 'no sexual activity' on all five questions of the EF domain for

which this answer was possible. The sixth question of the EF domain addressed the participants' confidence in their ability to achieve and/or maintain an erection and did not offer the option 'no sexual activity'. To be classified as suffering from 'severe ED', a participant's EF score had to lie between 1 and 10 according to the ED 'EF confidence' criteria.

The fourth approach was used to determine prevalence rates based on participant self-assessment: Definition 4: The participants' answer to the one-item question 'Do you think you have erectile dysfunction?' was used to determine the prevalence of the condition. As the prevalence rates determined here rely solely on the participant self-assessment, this group is referred to as ED 'subjective'.

The fifth approach was used to determine the prevalence rates for ED:

Definition 5: ED 'DSM-IV' was determined according to the Diagnostic and Statistical Manual of Mental Disorder criteria (DSM-IV). When determining the prevalence of ED according to DSM-IV, both the lack of erectile function (criterion A) and the emotional distress associated with it (criterion B) must be established before a diagnosis can be made.<sup>24</sup> Criterion A was met when at least one of the six items addressing erectile function was answered with 'sometimes' or less. Criterion B was met when the presence of suffering was confirmed, or one of the six items addressing the frequency and severity of suffering was answered with 'seldom'/'low' or more. Individuals were only assigned to the category ED in cases where both criteria A and B were met.

In addition, participants with self-reported ED were asked to state whether they had at any time sought treatment. They were given various answers to choose from: 'No, I'm not interested', 'No, but I am interested', 'Yes, medical', 'Yes, psychological', 'Yes, alternative', 'Yes, with spouse', 'Yes, with success', and 'Yes, but I cancelled treatment'.

#### *Data management and statistical analyses*

The completed questionnaires were scanned with a high-speed scanner. To ensure reliability and quality, all scanned data were checked for plausibility, verified manually if necessary, and transferred to an SPSS file. The statistical analyses were performed

with SAS version 8.2 (used for logistic regression) and SPSS version 11.0 (used for the remaining analyses). Overall age-adjusted prevalence rates were weighed according to the general population. For univariable analyses *t*-test was used for continuous variables and  $\chi^2$ -test for categorical variables. Statistical significance was stated at the 0.05-level.

## Results

Of 6000 mailed questionnaires, 1927 were returned. A total of  $n=1915$  of these were eligible for analysis, 12 having been excluded due to a large amount of missing data. Thus, the overall response rate was 32%. However, not all 1915 men answered every question, and not all questionnaires were included in each of the five approaches. Therefore, the sample sizes for the various variables varied from  $n=1915$  (for 'nationality') to  $n=1233$  (for ED 'EF active' approach). Table 1 shows the socio-demographic profile of the sample.

With regard to medical history, 75% reported one or more conditions (Table 2). The five different definitions yielded the following overall age-adjusted prevalence rates: 48% (ED 'EF all'), 31% (ED 'EF active'), 44% (ED 'EF confidence'), 24% (ED 'subjective') and 18% (ED 'DSM-IV'). Our findings regarding the prevalence of erectile dysfunction/ED by age groups are shown in Figure 1. In the ED 'EF all' definition, prevalence ranged from 28% in the lowest age group to 82% in the uppermost age group. In the ED 'EF active' definition, however, the prevalence of erectile dysfunction range from only 17 to 63% depending on the age group. The rates in the ED 'EF confidence' definition ranged from 22% for the lowest to 81% for the uppermost age group. The lowest prevalence for each age group was found in the ED 'DSM-IV' (between 7 and 26%) and the ED 'subjective' definition (between 9 and 51%). Important to note, however, is that the rates increased from age group to age group, regardless of the approach used to determine the prevalence rate.

Table 3 shows the 490 men who were sexually inactive over the past 4 weeks and, thus, excluded from the ED 'EF active' definition. Out of these 490 men, 125 (24%) reported their confidence in achieving and/or maintaining an erection to be high (62% in the lowest age group, 45% in the second, 25% in the third and 6% in the uppermost age group). The remaining 365 men (74%) reported their confidence in achieving and/or maintaining an erection to be low.

The distribution of the severity levels based on the ED 'EF confidence' approach is shown in Table 4. The percentage of 'severe ED' cases increased from the lowest to the uppermost age group from 16 to 61%, whereas the amount of 'mild ED' cases decreased from 51 to 18%.

**Table 1** Socio-demographic characteristics of the study population

Variables	n <sup>a</sup>	%
<b>Nationality (n = 1915)</b>		
German	1878	98
Other	37	2
<b>Age categories (n = 1905)</b>		
40–49	473	25
50–59	474	25
60–69	478	25
70–79	480	25
<b>Current marital status (n = 1892)</b>		
Single	209	11
Married	1287	68
Widowed	85	5
Divorced	311	16
<b>Partnership status (n = 1746)</b>		
No partner	271	15
Female partner	1446	83
Male partner	29	2
<b>Sexual orientation (n = 1888)</b>		
Heterosexual	1812	96
Homo/bisexual	76	4
<b>Current occupational status (n = 1608)</b>		
Employed	737	46
Not employed	871	54
Unemployed	180	18
Retired	634	64
Sick leave	179	18
School/training	4	0.2
<b>Highest level of education (n = 1781)</b>		
No graduation	45	3
Graduated 9th grade	554	31
Graduated 10th grade	401	22
Graduated 13th grade (high school)	211	12
University degree	570	32

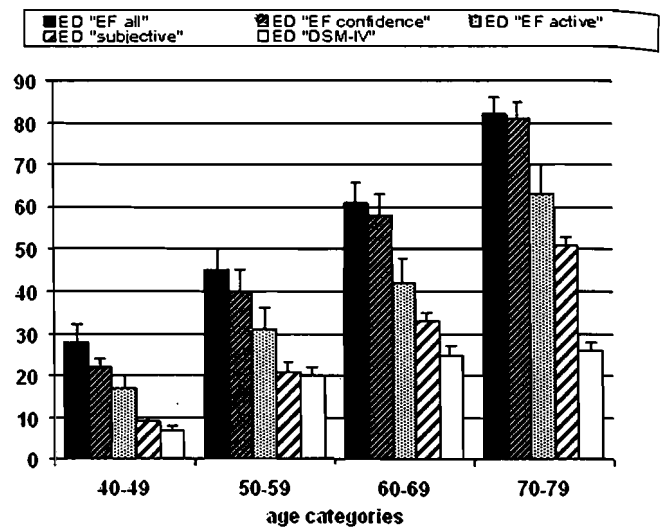
<sup>a</sup>Total 'n' vary due to missing information.

**Table 2** Prevalence of various medical conditions

Conditions (N = 1915) <sup>a</sup>	n	%
No condition	486	25
High blood pressure	536	28
Vertebral disease	431	23
Hypercholesterolemia	375	20
Heart disease	224	12
Prostate disease	216	11
Diabetes mellitus	152	8
Depression	87	5
Tumor	75	4
Stroke	60	3

<sup>a</sup>Multiple answers were possible.

Among those who self-reported having erectile dysfunction/ED, 39% were not interested in treatment, whereas 26% were interested in treatment and 35% had obtained treatment previously.



**Figure 1** Prevalence of erectile dysfunction/ED according to various approaches and age categories (in percent). ED 'EF all': based on the erectile function (EF) domain (including all men). ED 'EF confidence': based on the EF domain (including only sexually active men plus inactive men with a low confidence of achieving and maintaining an erection). ED 'EF active': based on the EF domain including only sexually active men. ED 'subjective': based on participant's subjective judgment on the presence of ED. ED 'DSM-IV': as defined in the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV). Confidence intervals of the proportions.

**Table 3** Confidence in achieving and maintaining an erection among those who reported no sexual activity in the past 4 weeks

Confidence (n = 490)	Age categories			
	40–49% (n = 57)	50–59% (n = 95)	60–69% (n = 139)	70–79% (n = 199)
Very high <sup>a</sup>	35	13	6	1
High <sup>a</sup>	27	32	19	5
Moderate <sup>b</sup>	26	25	25	20
Low <sup>b</sup>	5	16	13	19
Very low <sup>b</sup>	7	14	37	55

<sup>a</sup>Very high and high were summarized to high and excluded in the ED 'EF confidence' approach.

<sup>b</sup>Moderate, low and very low were summarized to low and included in the ED 'EF confidence' approach.

## Discussion

In the Berlin Male study the prevalence rates were assessed using five different definitions, yielding overall prevalence rates between 18 and 48%. Prevalence rates of erectile dysfunction/ED differed widely depending on the definition used. The main difference between the three definitions using the well established and validated EF domain.<sup>21–23</sup> was the inclusion of the subgroup men who had been

**Table 4** Severity of ED in age categories (in percent, based on the ED 'EF confidence' definition)

Severity	Age categories			
	40-49 (%)	50-59 (%)	60-69 (%)	70-79 (%)
Mild	51	44	33	18
Mild-moderate	23	17	16	13
Moderate	10	11	7	8
Severe	16	28	44	61

'sexually inactive' during the previous 4 weeks. Simply excluding these men from the analysis resulted in a decrease in overall prevalence from 48% (ED 'EF all') to 31% (ED 'EF active'). Doing so, however, is clearly problematic, as clinical experience has shown that sexual inactivity is often a consequence of low confidence in achieving and/or maintaining an erection due to having experienced a dysfunctional erection in the past.<sup>25</sup> In contrast, sexually inactive men with high confidence are presumably inactive for reasons unrelated to sexual functioning.<sup>23</sup> In order to address this subtle distinction, data from these 490 sexually inactive men were analyzed with regard to their confidence in achieving and/or maintaining an erection. The results showed that only 26% were highly positive, while 74% had only low confidence in achieving and maintaining an erection. Boer *et al.*<sup>25</sup> stated that men with erectile dysfunction were less content with their sexual life and had less confidence in sexual performance. With this in mind, the third definition (ED 'EF confidence') was designed to categorize sexually inactive men with low confidence as eligible for analysis, whereas sexually inactive men with high confidence in achieving and maintaining an erection were excluded. Reporting low confidence justifies the inclusion of responders when determining the prevalence of erectile dysfunction, as their inactivity may well be due to having experienced a dysfunctional erection at some point in the past. While prevalence following the ED 'EF all' definition might be overestimated, prevalence rates following the ED 'EF active' method might be underestimated. A fourth method involved self-assessment of ED ('ED subjective'). Compared to the results of all three EF domain approaches, ED prevalence may be underreported in self-assessment. This finding is consistent with other studies.<sup>10</sup> Hence, in the authors' view, the ED 'EF confidence' approach will yield the most realistic prevalence rates of erectile dysfunction.

However, none of the studies mentioned above considered DSM-IV criteria when determining prevalence of ED. Neither the prevalence rate of erectile dysfunction reported in this study using the three different definitions based on the EF domain, nor

the self-reported prevalence rates allow us to evaluate the clinical relevance of the condition. As erectile dysfunction is not a life-threatening disease, the most important reason for possible treatment might be emotional distress or interpersonal problems. Research projects investigating the impact of different chronic diseases on sexuality and partnership based on the DSM-IV criteria clearly reveal that sexual dysfunctions are not necessarily associated with emotional distress.<sup>26-28</sup>

Thus, using a fifth definition based on DSM-IV criteria, men with erectile dysfunction associated with emotional distress (measured over the last 6 months) were identified. This approach allows us to differentiate between erectile dysfunction (without consideration of emotional distress) and ED (with consideration of emotional burden).<sup>29</sup> Following the DSM-IV criteria, the age-adjusted total was only 18%. The data obtained with the different methods show a high proportion of men with erectile dysfunction but without distress and thus without clinical relevance. This may explain the varying attitudes towards treatment between men diagnosed using the EF domain-based approach and those diagnosed with the DSM-IV-based approach. From a clinical point of view, it seems essential to incorporate in a standardized instrument the question of whether erectile dysfunction is associated with emotional distress. Further discussion is required about how long the observation period should be (e.g. 1, 3 or 6 months) and how to measure emotional distress in an effective and reliable fashion.

#### Limitations

Some general weaknesses of the study should be pointed out. The response rate was only 32%. To evaluate the different categories of erectile dysfunction and ED, the questionnaire was quite long, thereby perhaps reducing the response rate. Boer *et al.*<sup>19</sup> stated that the number of questions appears to affect the response rate. Therefore, we suggest the use of shorter instruments for further studies. In addition, the sensitive nature of the topics in general may have reduced participation rates. As the response rate in each age categories was similar (approximately 25% in each age group), it was possible to adjust prevalence rates in each category for overall prevalence rates. A selection bias cannot be excluded and no statement can be made regarding the applicability of our data to the German population and for other populations of the world.

As the study was conducted anonymously, participants who did not answer every question could not be contacted again. Thus, it was impossible to reduce the amount of missing data. As data was collected solely via self-completed questionnaire, the assessment was limited to self-report and, as a consequence, may have led to some biased results.

## Conclusions

In this study, we focus on the marked influence of different definitions on the prevalence rates. As one data set produced five different prevalence rates of erectile dysfunction/ED, depending on the definition used, it is important to agree upon a uniform way of assessing erectile dysfunction and ED to make prevalence rates comparable across studies. There is a need for a standardized concise questionnaire including the definition of sexual activity, the timeline investigated (4 weeks or 6 months), the self-report question, the length of the questionnaire and the impact of distress. Comparability of published prevalence rates will be important to assess the epidemiological magnitude of the disorder as well as for designing adequate therapeutic and public health strategies.

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