COMMENTARY

Subclinical Erectile Dysfunction: Proposal for a Novel Taxonomic Category in Sexual Medicine

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ABSTRACT-

The definition of erectile dysfunction currently used and accepted worldwide does not encompass all possible changes to male erection. Partial, temporary, or episodic absence of erection is not considered as true erectile dysfunction. This leads to a lack of diagnosis and therapy and perhaps even the risk of the subsequent development of overt impotence. The lack of an evidence-based diagnosis of such a condition may be due to the widespread, pernicious self-prescription of erection drugs, obtained from the illegal market. To define the pathological condition of men experiencing a lack of erection who are unaffected by erectile dysfunction, we propose herein a new taxonomic category, based on new sexological criteria. In addition, we suggest research into biochemical markers to define this condition, which we have named *subclinical erectile dysfunction*. Jannini EA, Lenzi A, Isidori A, and Fabbri A. Subclinical erectile dysfunction: Proposal for a novel taxonomic category in sexual medicine. J Sex Med 2006;3:787–794.

Key Words. Male Erectile Disorder; Oral Vasoactive Agents; Psychological Assessment of Sexual Dysfunction

Introduction

Penile erection has a very important impact on men [1,2]. Even partial or intermittent erection failure batters a man's sense of masculinity, with profound effects on his quality of life.

Analyzing the sexual life of a large cohort of middle-class and happily married couples, Frank et al. surprisingly demonstrated in the *New England Journal of Medicine* about 30 years ago that sexual problems are highly prevalent even in sexually healthy people [3]. In "normal" couples, not seeking help for marital or sexual problems, and reporting happy, satisfying marital and sexual relations, a 15-page sexual questionnaire (KDS-15) elicited some difficulties in getting (7%) and maintaining (9%) an erection. This group consists of neither patients with erectile dysfunction (ED) nor the general population, which includes subjects both with and without sexual problems. How should we define substantially healthy, ED-free

subjects, who nevertheless have some erectile difficulties? The aims of this article are to suggest clinical guidelines to recognize and classify this condition and to encourage the research of clinical markers.

Do Prevalence Studies Represent the Whole World of Erectile Failures?

The largest, most cited study on the prevalence of ED, the Massachusetts Male Aging Study (MMAS), [4] asked respondents to characterize themselves as not impotent, minimally impotent, moderately impotent, and completely impotent. On the basis of this self-rated ED, a prevalence of 52% was found in 1,290 men aged 40–70 years. Although the authors argued that impotence is best defined by the individual's assessment of his own situation in simple terms (minimal, moderate, or complete impotence), this figure does not correspond to common clinical experience. A more

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recent, larger international survey investigating the attitudes, behaviors, beliefs, and sexual satisfaction of 27,500 men and women aged 40-80 years [5] gives an indication of reported prevalence rates across various European regions and beyond. Erectile difficulties were reported in 28% of men (only a little more than half that demonstrated in the MMAS). The prevalence of ED greatly increased with age and was the most frequent disorder among the oldest men. While not a true epidemiological survey, the Global Study of Sexual Attitudes and Behaviors (GSSAB) can be considered as an international poll of people's attitudes toward sex and sexual dysfunction. As sexual health issues are strongly characterized by culture and religion, the same terminology may be interpreted in different ways across countries and/or regions. Clearly, ED is perceived, reported, and treated differently on the basis of such sociocultural factors. Local and regional variations identified in the GSSAB must therefore always be considered in the context of the various cultural, religious, and political influences. Another fundamental limitation with this survey stems from the fact that the youngest participants were 40 years old, an age when the incidence of ED is-or should be-higher than in younger men. Conversely, it must also be considered that cultural and age-related factors mean that mature men may be more likely to seek professional help for their sexual problems [6].

The sharp discrepancy between these two surveys may be explained by the lack of a taxonomic definition for ED as well as cultural differences in the perception of impotency disorders. While the definition of severe, or total ED ("completely impotent" in the MMAS) is self-explanatory and crystal clear, the definition of moderate ED is less obvious: it could in fact be a matter of time (frequency of failure) or of erection intensity. Obviously, such uncertainty is even worse when dealing with mild impotence. Another important aspect regards a differing perception of the symptom between the man and his partner. Such differences further account for diagnostic problems.

The severity of ED has been successfully quantified by the 15-item International Index of Erectile Function (IIEF) [7], the most frequently used questionnaire for the evaluation of male sexual function. Its abbreviated version, IIEF-5—also called the Sexual Health Inventory for Men (SHIM)—is suitable for diagnosis of the severity of ED [8]. The IIEF-5 disease severity scores are 22–25 (inclusive) for no ED, 17–21 for mild, 12–

16 for mild-to-moderate, 8–11 for moderate, and 5–7 for severe ED, with the reference period being the previous 6 months [9]. The SHIM cannot be applied to men who have not attempted sexual intercourse or have had no opportunity to engage in sexual activity. Its primary purpose is screening and diagnostic severity assessment in clinical practice, and in clinical trials on ED as part of the study's inclusion criteria. Prevalence studies show that usually more than one-third of men suffering from ED have only a mild form that, once diagnosed, is worthy of treatment.

Some men experience troublesome erectile failures as separate events from the degrees of ED defined above, hidden in the non-ED area of SHIM. The question is how to reveal, whether to diagnose, and when to treat such condition [10].

Toward a New Taxonomy

On the grounds of a "historical" Consensus Development Conference on Male Impotence, convened at the National Institutes of Health (NIH), Bethesda, MD, in December 1992, ED is universally defined as the chronic impossibility to have or to maintain a full erection in the presence of proper erotic stimuli [11]. Impotence is generally classified on an etiological basis into *organic* and *psychogenic*. However, even if the evidence that the brain is the main sexual organ cannot be denied, in its meritorious work, Sachs argued that the adjective psychogenic, albeit largely used, is inappropriate in the classification of sexual dysfunctions [12,13]. Irrespectively of their causes, all sexual dysfunctions are stressful per se and a source of psychological disturbances [14]. Can a difficulty in achieving erection, or suboptimal rigidity, or suboptimal ability [15] to sustain an erection be classified as true ED? That is, can it be counted as a dysfunction or disease? Not in the NIH's definition, nor in the patient's perception: Frank et al.'s subjects considered themselves to be essentially healthy [3]. Clinical experience suggests that for many subjects, this condition can be at least worrying, if not downright frustrating. Does this deserve medical attention, diagnosis, and treatment?

The concept of a subclinical disease or dysfunction is growing in modern medicine in general (more than 14,000 Medline entries use this term), endocrinology in particular, and now in medical sexology. We propose that the condition of subjects fulfilling the sexological criteria defined in Table 1 be named *subclinical ED* (SED). This term is deliberately reminiscent of subclinical hypothy-

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