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Premenstrual disorders: bridging research and clinical reality.

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INTRODUCTION: As with a number of emotional disorders, premenstrual complaints lie on a continuum dictated by severity, number and type of symptoms experienced. Women with premenstrual dysphoric disorder (PMDD) generally constitute the most symptomatic subgroup among those experiencing premenstrual symptoms. Included in the Diagnostic and Statistical Manual IV (DSM-IV) criteria for PMDD is a requirement for a minimum of 5 symptoms and for confirmation of these symptoms over two months by concurrent symptom ratings. These requirements likely influence critical patient characteristics rendering trial participants and typical patients seeking treatment, very different. METHODS: Women were recruited from 6 primary care obstetric-gynecological practices for participation in an open trial assessing the effectiveness of a serotonin reuptake inhibitor as a treatment for subsyndromal (3-4 symptoms) and syndromal (>4 symptoms) PMDD. Women were screened with the Brief Patient Health Questionnaire and Last Menstrual Period Module. Eligible women were invited to chart symptoms daily for one cycle using the Daily Record of Severity of Problems. Current comorbidity was allowed if women experienced a cyclic change in mood and behavioral symptoms. RESULTS: 47% of 904 women screened in practice settings (n=426) endorsed current PMS symptoms. Of this group, 174 (41%) were not interested in receiving treatment through a research study, 152 (36%) were not eligible to receive treatment (symptoms not severe enough, subsequently declined premenstrual symptom worsening, were already taking a psychotropic or wanted to conceive), 10% were lost to follow-up or had incomplete questionnaires, and 41 (10%) agreed to chart. Of women who charted, 9 (22%) verified symptoms. 93 women (22% of the 426) had comorbid MDD, 23 (5.4%) had minor depressive disorder and 61 (14%) had panic disorder. 24% of women with possible PMDD endorsed suicidal thoughts at any level (several days, more than half the days or every day); 20% endorsed these thoughts for several days. These results are used as a springboard to discuss how treatment results from efficacy trials may differ from treatment results that include women seeking treatment in usual care settings. CONCLUSION: These preliminary findings show that many women in primary care ob-gyn settings endorse serious premenstrual symptoms and have concurrent psychiatric conditions. Despite this, interest in study participation was low. This occurred even though the current study employed procedures that were much less rigorous than those used in the typical efficacy study. More work is needed to explore how the selectivity of patients included in clinical trials may bias estimates of how effective many agents will be in actual clinical practice.