Prevalence and implications of anxiety in polycystic ovary syndrome: results of an internet-based survey in Germany

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BACKGROUND: Comparatively little attention has been paid to the symptoms of anxiety in polycystic ovary syndrome (PCOS), although anxiety disorders constitute the most common psychiatric diagnoses among endocrine patients and in the general population. Therefore, our goal was to address the prevalence, determinants and implications of anxiety alone or anxiety in combination with depression in German women with PCOS.

METHODS: In this nation-wide, internet-based survey, anxiety and depression (Hospital Anxiety and Depression Scale, HADS) and quality of life (SF-12) were assessed together with sociodemographic information and clinical PCOS symptoms in 448 PCOS women.

RESULTS: Of the patients, 34% showed clinically relevant HADS anxiety scores and 21% had clinically relevant HADS depression scores. Quality of life was significantly impaired in PCOS women with anxiety (P < 0.001), in particular, in women with comorbid anxiety and depression (P < 0.001). The risk for clinically relevant HADS anxiety scores was significantly enhanced in PCOS women with acne (odds ratio (OR) = 1.52; 95% confidence interval (CI) = 1.03–2.52) and an unfulfilled wish to conceive (OR = 1.50; 95% CI = 1.01–2.23).

CONCLUSIONS: PCOS women may be at an increased risk for clinically relevant anxiety, and comorbid anxiety and depression is also very common. Anxiety contributes to impaired quality of life in PCOS. Given the high prevalence and the serious implications, and the availability of effective treatment options given proper diagnosis, clinicians should be more aware of anxiety disorders in women with PCOS.

Key words: PCOS / anxiety / depression / quality of life

Introduction

Polycystic ovary syndrome (PCOS) is a common endocrine disorder affecting ~6% of women of reproductive age (Knochenhauer et al., 1998; Asuncion et al., 2000; Azziz et al., 2004). It is characterized by both gynaecological and endocrine symptoms, including chronic anovulation, hyperandrogenism, the metabolic syndrome and insulin resistance (Carmina, 2003; Azziz, 2004; Chang, 2004; Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group, 2004). It is well-established that PCOS women suffer from impaired emotional well-being and markedly reduced quality of life (Himelein and Thatcher, 2006a; Janssen et al., 2008). In fact, several studies suggest that a proportion of PCOS patients may present with clinically relevant psychopathology (Hollinrake et al., 2007; Kerchner et al., 2008; Mansson et al., 2008). The majority of studies have thus far focused on symptoms of depression, which indeed constitutes a comorbidity in a large proportion of patients (Rason et al., 2003; Weiner et al., 2004; Himelein and Thatcher, 2006b; Barnard et al., 2007; Hollinrake et al., 2007; Benson et al., 2008).

Comparatively little attention has been paid to the symptoms of anxiety in PCOS, although anxiety disorders constitute the most common psychiatric diagnoses among treated endocrine patients (Sonino et al., 2004) as well as in the general population (Stein, 2006). Anxiety and social fears may cause social isolation and impair quality of life (Kessler, 2003), and enhance the risk of additional psychiatric disorders, e.g. depression, and suicide attempts (Culpepper, 2006; Stein, 2006) which have an increased prevalence in PCOS patients (Mansson et al., 2008). Indeed, Mansson et al. (2008) recently reported that the life time incidence of social phobia was 27%, and Kerchner et al. (2008) documented a prevalence of 11.6% of anxiety syndromes in PCOS women.
The goal of this study was to assess the prevalence and implications of anxiety in a large sample of PCOS patients. In this internet-based survey of German PCOS women, we tested the hypothesis that in addition to symptoms of depression, anxiety is prevalent in PCOS. Further, we hypothesized that anxious PCOS women demonstrate reduced quality of life, particularly in the presence of comorbid depression.

Materials and Methods

Participants and procedure
Data were collected using an internet-based questionnaire (see below). The link was posted on the homepage of the German PCOS patient support group (http://www.pcos-selfbshlife.org), which provides information about the diagnosis and treatment of PCOS as well as about meetings and activities of local PCOS support groups. In Germany, multiple support groups in all larger cities and/or regions are organized together in a network that was initiated and coordinated by the members of the PCOS working group (O.E.J., S.H. and S.T.). As part of this initiative, the German PCOS website was created, and its contents are continuously updated by the members of our group. Background information on the goals of the study was available on the website. However, to prevent access for non-patients, the link that opened the questionnaire was only accessible to registered users of the German PCOS support group. Each participant received an individual password that allowed access to the questionnaire and offered the opportunity to re-enter and complete the questionnaire at a later time-point, if necessary. Participants were also informed that data were collected anonymously and stored on a separate server (Hogrefe Testsystem, Göttingen, Germany).

The PCOS diagnosis was confirmed based on self-reported data (see below for details on data collection). Respondents were only included if they stated that the diagnosis of PCOS had been established by an endocrinologist or a gynaecologist. Further, the study only included respondents who were aged 16–45 years and who reported medically confirmed symptoms according to the Rotterdam criteria (Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group, 2004), i.e. two of the following criteria: oligomenorrhea (cycles lasting longer than 35 days) or amenorrhea (less then two menstrual cycles in the past 6 months), hyperandrogenism (hirsutism, obvious acne, alopecia) and polycystic ovaries. By basing our confirmation of the diagnosis on self-report and physical (rather than biochemical) signs of hyperandrogenism, the proportion of PCOS with only elevated testosterone and polycystic ovaries or oligo-/amenorrhea may be under-represented in this sample. Given the nature of the study, we note that it was not feasible to reliably exclude comorbid endocrine conditions.

The survey took place from December 2006 until August 2007 and was approved by the Ethics Committee of the University of Duisburg-Essen.

Internet questionnaire
The questionnaire was programmed and provided using an internet-based test platform (Hogrefe Testsystem). It covered sociodemographic, clinical and psychological areas. Participants were instructed to complete the requested information or to check the appropriate answers, respectively. Sociodemographic information, including age, family status, education and employment were assessed. To confirm the PCOS diagnosis, the presence of medically confirmed symptoms was evaluated according to the Rotterdam criteria (answering options are shown in brackets): cycle disturbances (i.e. cycles <35 days; cycles ≥35 days; less then two menstrual cycles in the past 6 months; not sure), presence of hirsutism, obvious acne, alopecia (each yes/no) and polycystic ovaries (yes/no/not sure). Body weight and body size were also recorded, and body mass index (BMI) was calculated as [body weight in kilogram/(body size in metre)²].

Anxiety and depression, as well as health-related quality of life were assessed using online versions of validated questionnaires (Hogrefe Testsystem, for detailed information, see below). In addition, participants were asked if they had ever been in psychotherapy (yes/no).

Anxiety and depression
Anxiety and depression were assessed using the German version of the Hospital Anxiety and Depression Scale (HADS) (Herrmann-Lingen et al., 2005). The HADS is designed to evaluate anxiety and depression in patients with somatic diseases. The HADS consists of 14 items that address various aspects of depression and anxiety in the past 7 days. The scale can be divided into two subscales (anxiety and depression). Both subscales contain seven Likert-scaled items, with sum scores ranging from 0 to 21. Higher sum scores indicate more anxiety and depression, respectively. Sum scores <8 indicate normal range, scores 8–10 reflect mild alterations and scores ≥11 indicate clinical relevance of symptoms. The sensitivity (83.3%) and specificity (61.5%) for the identification of psychiatric cases were acceptable (Herrmann-Lingen et al., 2005). The HADS subscales have previously shown a comparatively high intercorrelation of r = 0.65 (Herrmann-Lingen et al., 2005); however, the discriminatory validity is confirmed by results of the factor analysis.

Health-related quality of life
The SF-12, the short version of the widely used SF-36, was used to assess health-related quality of life (Bullinger and Kirchberger, 1998). The SF-12 addresses the impact of physical health complaints on various activities of daily life, including housework, social life and work life, as well as on vitality and emotional well-being. It contains 12 items that explain health-related quality of life (Bullinger and Kirchberger, 1998). Scoring results in two global health measures, i.e. the physical and psychological sum scores. Lower scores indicate poorer physical and psychological quality of life, respectively.

Statistical analyses
Questionnaires were scored and analysed according to the published guidelines (Bullinger and Kirchberger, 1998; Herrmann-Lingen et al., 2005). Data were tested for normality using Kolmogorov–Smirnov test, and log transformations were conducted where appropriate (i.e. for SF-12 and HADS subscales).

(1) The proportion of participants with clinically relevant anxiety and/or depression was calculated based on HADS cut-off scores, i.e. subscale scores ≥11 (Herrmann-Lingen et al., 2005). Additionally, group means of the HADS subscales were compared with two different female German reference populations (German norm) using one-sample t-tests, which were published in the German handbook of the HADS (Herrmann-Lingen et al., 2005) and by Hinz and Schwarz (2001), respectively.

(2) Initially, group means of SF-12 subscales were compared with the respective female German reference populations (German norm) using one-sample t-tests. Subsequently, to assess the impact of anxiety symptoms on quality of life, the sample was divided into groups based on HADS scores based on the following considerations: participants may either present with elevated scores on ‘one’ of the scales of the HADS, indicating clinically relevant anxiety or depression, respectively, or they may present with elevated scores on ‘both’ scales, indicating comorbid anxiety and depression. To take into account that the latter group may be particularly affected in quality of life, we looked at this group separately. Hence, participants were...
Results

Sociodemographic and clinical characteristics

A total of \( n = 466 \) women completed the online questionnaire. Out of those, 16 women were excluded as they did not meet Rotterdam criteria and 2 were excluded as they were over 45 years of age. Hence, data from 448 PCOS women were included. Table I refers to sociodemographic characteristics, including age, BMI, family status, education and employment. Regarding PCOS symptoms, 65.6% of the participants \( (n = 294) \) reported hirsutism, 43.5% \( (n = 195) \) reported acne, 55.6% \( (n = 249) \) had an unfulfilled wish to conceive and 54.0% \( (n = 242) \) were obese.

Prevalence of anxiety and depression and utilization of psychotherapy

Of the participants, 34% \( (n = 153) \) demonstrated elevated HADS anxiety scores (i.e. HADS anxiety subscale \( \geq 11 \)) and 20.5% \( (n = 92) \) showed elevated HADS depression scores (i.e. HADS depression subscale \( \geq 11 \)). There was 15% \( (n = 69) \) who scored above the cut-offs for both subscales, indicating comorbid anxiety and depression (Fig. 1). Hence, given this overlap, altogether 39% \( (n = 176) \) were at psychiatric risk indicated by pathological HADS scores. When compared with normative data for German females (Hinz and Schwarz, 2001; Herrmann-Lingen et al., 2005), mean HADS scores were significantly elevated in PCOS \( (P < 0.001) \), Table II). Approximately one-third of the participants \( (34.8%; n = 156) \) reported that they had previously been in psychotherapy. Among participants with pathological anxiety scores, 43.8% \( (n = 67) \) had been in psychotherapy, and among participants with pathological depression scores 52.2% \( (n = 48) \) had been treated with psychotherapy.

Implications for quality of life

Initially, the psychological and physical aspects of quality of life (SF-12 psychological and physical sum scores) in this PCOS sample were compared with the female German normative population. Whereas PCOS women were characterized by significantly reduced psychological quality of life \( (P < 0.001) \), physical quality of life was unaltered (Table II). Subsequently, to assess the impact of anxiety symptoms on quality of life, the sample was divided into four subgroups based on HADS scores. All groups with pathological HADS scores demonstrated markedly reduced psychological quality of life \( (F = 57.7, P < 0.001) \), Fig. 2). Notably, anxiety led to impaired psychological quality of life independent of depression (post hoc Scheffé test: for PCOS with anxiety versus unaffected PCOS: \( P < 0.001 \)). The lowest psychological quality of life, however, was observed in participants with comorbid anxiety and depression (post hoc Scheffé test: for PCOS with anxiety and depression versus unaffected PCOS: \( P < 0.001 \)).

The physical aspects of quality of life were similarly reduced in participants with pathological HADS scores \( (P < 0.001) \). Post hoc comparisons revealed a significantly lower quality of life in PCOS women with depression (post hoc Scheffé test: \( P < 0.05 \)) and PCOS women with comorbid anxiety and depression (post hoc Scheffé test: \( P < 0.01 \)) compared with unaffected participants. Physical quality of life was comparable between women with PCOS with anxiety and unaffected PCOS.

Additional ANCOVAs revealed that BMI was a significant covariate for physical \( (F = 66.3; P < 0.001) \) as well as psychological \( (F = 7.3; P < 0.01) \) quality of life scores; however, the group differences above remained significant after controlling for BMI.

Impact of individual PCOS symptoms on anxiety and depression risk

The risk for clinically relevant anxiety was significantly enhanced in participants with acne \( (x^2 = 4.4; P < 0.05) \) and in women reporting an unfulfilled wish to conceive \( (x^2 = 4.0; P < 0.05) \) (for ORs, see Table III). However, anxiety risk was not significantly elevated in participants with obesity or hirsutism. The risk for clinically relevant depression was significantly higher in participants who were obese \( (x^2 = 5.6; P < 0.05) \), or who reported hirsutism \( (x^2 = 6.8; P < 0.01) \) or acne \( (x^2 = 4.5; P < 0.05) \) (for ORs, see Table III). Interestingly, an unfulfilled wish to conceive was not associated with depression risk.

Discussion

The goal of this internet-based survey was to address the prevalence, determinants and implications of anxiety in German PCOS women.
The main findings were the high prevalence of clinically relevant anxiety in PCOS women and the reduction of quality of life in patients suffering from anxiety, especially in women with comorbid anxiety and depression.

The prevalence of anxiety was high in this large cohort of PCOS women. In fact, more than one-third of the participants suffered from clinically relevant anxiety symptoms, which corresponds to a 3-fold increase in the prevalence compared with the German reference population (Herrmann-Lingen et al., 2005). This finding is consistent with recent evidence from Mansson et al. (2008) who assessed DSM-IV (Diagnostic and Statistic Manual of Mental Disorders) Axis-I diagnoses and found a significantly elevated life-time incidence of social phobia in PCOS patients (27%; OR: 18.0, 95% CI = 2.2–144), as well as a trend for an elevated incidence of generalized anxiety disorder (13%; OR: 7.3, 95% CI = 0.86–63). Given that the authors used structured clinical interviews to assess psychopathology, they were only able to study a comparatively small sample of PCOS patients treated at university outpatient units. Our questionnaire-based findings in a much larger, self-selected sample of PCOS women complement their results. Participants of our study also reported a high life time utilization of psychotherapy. In fact, one-third of our sample indicated that they had previously undergone some type of psychotherapeutic treatment, and this percentage was higher in participants with clinically relevant anxiety symptoms (43.8%) or depression symptoms (52.5%). These data, albeit crudely measured and non-specific with regard to type or duration of treatment,

### Table II

<table>
<thead>
<tr>
<th>PCOS</th>
<th>German norm</th>
<th>*P</th>
</tr>
</thead>
<tbody>
<tr>
<td>HADS anxiety, mean (SD)</td>
<td>9.0 (4.1)</td>
<td>6.3 (3.2)*/4.6 (3.2)<em>b &lt; 0.001</em></td>
</tr>
<tr>
<td>HADS depression, mean (SD)</td>
<td>7.2 (4.2)</td>
<td>3.2 (2.6)*/3.2 (3.1)<em>b &lt; 0.001</em></td>
</tr>
<tr>
<td>SF-12 physical sum score, mean (SD)</td>
<td>48.3 (8.7)</td>
<td>47.9 (9.3) ns</td>
</tr>
<tr>
<td>SF-12 psychological sum score, mean (SD)</td>
<td>38.3 (10.8)</td>
<td>51.3 (8.4) &lt; 0.001</td>
</tr>
</tbody>
</table>

*aNormative data from Herrmann-Lingen et al. (2005).*  
b*Normative data from Hinz and Schwarz (2001).*  
*PCOS versus data from Herrmann-Lingen et al. (2005) and Hinz and Schwarz (2001), respectively.*

Figure 1: Frequency distribution of participants presenting with normal HADS (unaffected PCOS), PCOS with anxiety, PCOS with depression, or PCOS with anxiety and depression (i.e. participants with HADS subscale score ≥11).

Figure 2: Quality of life (SF-12 physical (left) and psychological (right) sum scores) in women with unaffected PCOS, PCOS with anxiety, PCOS with depression or PCOS with anxiety and depression (i.e. participants with HADS subscale score ≥11). SF-12 scores of the German female normative population are additionally shown (for results of group comparisons, see Table II). *P < 0.05 versus unaffected PCOS women, ***P < 0.001 versus unaffected PCOS women.
There is evidence to support the concept that anxiety is a risk factor for the development of depressive disorders (Belzer and Schneier, 2004; Culpepper, 2006; Stein, 2006). About 20% of our participants showed elevated HADS depression levels (i.e. HADS depression score ≥ 11), which is actually somewhat lower than the prevalence of depressive symptoms in previous studies ranging from 35 to 67% (Rasgon et al., 2003; Barnard et al., 2007; Hollinrake et al., 2007). Nevertheless, depression is undoubtedly a serious complication in a proportion of PCOS women, which is highlighted by an increased number of suicide attempts recently reported in PCOS patients (Mansson et al., 2008). Whether or not anxiety symptoms contribute to, maintain, or even exacerbate depression in PCOS cannot be determined by our cross-sectional data. However, our data indicate that a proportion of PCOS women (i.e. 15%) present with a comorbidity of anxiety and depression, which has important treatment implications (Belzer and Schneier, 2004).

Anxiety constitutes a strong predictor of functional impairments and has major effects on role functioning and quality of life in patients with anxiety disorders (Kessler, 2003; Stein, 2006). Accordingly, participants with elevated HADS anxiety levels reported significantly impaired psychological quality of life. This was especially true for those with both clinically relevant anxiety and depression symptoms. Decreases in psychological, as well as in physical, areas of quality of life in PCOS patients have previously been reported (Himelein and Thatcher, 2006a; Janssen et al., 2008). The determinants of reductions in quality of life in PCOS remain incompletely understood. However, there is converging evidence to suggest that physical aspects of quality of life may be best predicted by obesity and hirsutism (Hahn et al., 2005; Trent et al., 2005; Elsenbruch et al., 2006), whereas psychological components of quality of life may be more closely related to psychological impairment. In a previous study in PCOS patients from our outpatient clinic, we demonstrated the importance of emotional distress in psychological quality of life (Elsenbruch et al., 2006). The present findings strengthen these results and emphasize the pivotal role of anxiety.

It remains unclear what elicits and/or maintains high levels of anxiety in PCOS women. In general, PCOS women fail to conform with societal norms for outer appearance. Cycle disturbances and infertility may interfere with female role expectations (Kitzinger and Willmott, 2002), may ultimately contribute to social fears and social withdrawal. Specific PCOS symptoms may also contribute to anxiety. Indeed, PCOS patients suffer from symptoms that have previously been related to anxiety in other patient populations, including hirsutism (Lipton et al., 2006), acne (Yazici et al., 2004), obesity (Petry et al., 2008) and involuntary childlessness (Lechner et al., 2007). Accordingly, we observed that patients with acne and/or an unfulfilled wish to conceive had an elevated risk for anxiety. However, based on our data, we cannot exclude that elevated anxiety risk in PCOS women with an unfulfilled wish to conceive may rather be attributable to the emotional sequels of unsuccessful infertility treatment. Generally, the contribution of individual PCOS symptoms to anxiety risk reported herein should be interpreted with caution since most patients present with a combination of PCOS symptoms, which may further enhance the risk for anxiety. Clearly, since we did not analyse the effects of various combinations of clinical symptoms, this aspect of our analysis should be regarded as explorative.

The advantage of this internet-based questionnaire via the homepage of the German PCOS self-support group allowed the assessment of a large sample of PCOS women. Although a similar internet-approach has previously been used by others (Barnard et al., 2007), there are several important drawbacks that must be considered. Although a log-in was feasible only for registered users of the PCOS homepage and only participants who stated medically confirmed PCOS symptoms were included, the presence or absence of specific PCOS symptoms was based on self-report. As a result, these findings describe a population that was not fully characterized clinically, and this may theoretically have led to the inclusion of women who misreported their diagnosis as well as of women with comorbid medical conditions. In addition, by basing confirmation of the diagnosis on self-report and physical (rather than biochemical) signs of hyperandrogenism, the proportion of PCOS with only elevated testosterone and polycystic ovaries or oligo-/amenorrhea may be under-represented in this sample.

Another important consideration is the possibility of a self-selection bias for this survey, which may limit the generalizability of our findings. Patients who actively seek support through a support group and use the associated internet forum may not be representative of the entire PCOS patient population. Whether this specific group is psychologically more or less burdened compared with patients who cope differently remains unclear. However, it appears unlikely that the prevalence of psychiatric symptoms is overestimated in this study since the prevalence of depression symptoms reported herein was in fact lower than the prevalence reported in other studies (Rasgon et al., 2003; Barnard et al., 2007; Hollinrake et al., 2007). Finally, internet use is related to educational and socioeconomic

### Table III: ORs for HADS anxiety or HADS depression scores ≥ 11 indicating risk for clinical relevant anxiety disorder or depression in relation to PCOS symptoms

<table>
<thead>
<tr>
<th>PCOS symptom</th>
<th>% (n)</th>
<th>P</th>
<th>OR (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Elevated HADS anxiety score (n = 153; 34.2%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obesity (BMI ≥ 30)</td>
<td>Yes 36.4 (71)</td>
<td>ns</td>
<td>1.29 (0.87–1.92)</td>
</tr>
<tr>
<td></td>
<td>No 30.7 (75)</td>
<td></td>
<td>1.00 ns</td>
</tr>
<tr>
<td>Hirsutism</td>
<td>Yes 38.7 (108)</td>
<td>ns</td>
<td>1.41 (0.92–2.14)</td>
</tr>
<tr>
<td></td>
<td>No 29.2 (45)</td>
<td></td>
<td>1.00 ns</td>
</tr>
<tr>
<td>Acne</td>
<td>Yes 39.5 (77)</td>
<td>&lt;0.05</td>
<td>1.52 (1.03–2.52)</td>
</tr>
<tr>
<td></td>
<td>No 30.0 (76)</td>
<td></td>
<td>1.00 ns</td>
</tr>
<tr>
<td>Unfulfilled wish to conceive</td>
<td>Yes 38.2 (95)</td>
<td>&lt;0.05</td>
<td>1.50 (1.01–2.23)</td>
</tr>
<tr>
<td></td>
<td>No 29.1 (58)</td>
<td></td>
<td>1.00 ns</td>
</tr>
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**Elevated HADS depression score (n = 92; 20.5%)**

<table>
<thead>
<tr>
<th>PCOS symptom</th>
<th>% (n)</th>
<th>P</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity (BMI ≥ 30)</td>
<td>Yes 24.6 (48)</td>
<td>&lt;0.05</td>
<td>1.77 (1.10–2.85)</td>
</tr>
<tr>
<td></td>
<td>No 15.6 (38)</td>
<td></td>
<td>1.00 ns</td>
</tr>
<tr>
<td>Hirsutism</td>
<td>Yes 24.1 (71)</td>
<td>&lt;0.01</td>
<td>2.02 (1.18–3.43)</td>
</tr>
<tr>
<td></td>
<td>No 13.6 (21)</td>
<td></td>
<td>1.00 ns</td>
</tr>
<tr>
<td>Acne</td>
<td>Yes 25.1 (49)</td>
<td>&lt;0.05</td>
<td>1.64 (1.03–2.60)</td>
</tr>
<tr>
<td></td>
<td>No 17.0 (43)</td>
<td></td>
<td>1.00 ns</td>
</tr>
<tr>
<td>Unfulfilled wish to conceive</td>
<td>Yes 19.3 (48)</td>
<td>ns</td>
<td>0.84 (0.53–1.33)</td>
</tr>
<tr>
<td></td>
<td>No 22.1 (44)</td>
<td></td>
<td>1.00 ns</td>
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</table>
status. Hence, the proportion of PCOS women with a relatively high level of education may be over-represented in our internet-based survey, as reflected by the high percentage of participants with a college degree (i.e. ‘German Abitur’).

In summary, a large proportion of PCOS women are at increased risk for clinically relevant anxiety. Anxiety leads to reduced psychological quality of life and likely contributes to functional impairments and social isolation, especially in women with comorbid anxiety and depression. Given the high prevalence and the serious implications of anxiety and depression in PCOS women, clinicians should be aware of these psychiatric comorbidities and ensure that patients receive adequate psychotherapeutic and/or pharmacologic treatment.

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