CHAPTER V

SUMMARY

The term "premenstrual disorders" covers a spectrum of premenstrual combinations, from mild premenstrual syndrome (PMS) to premenstrual disorder (PMDD). Millions of women of reproductive age have recurrent emotional, cognitive, and physical symptoms related to their menstrual cycles. These symptoms often recur discretely during the luteal phase of the menstrual cycle and may significantly interfere with social, occupational, and sexual functioning. Premenstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome (PMS), is diagnosed by the pattern of symptoms. According to a report by the Committee on Gynecologic Practice of the American College of Obstetricians and Gynecologists 1995, up to 80 percent of women of reproductive age have physical changes with menstruation; 20 to 40 percent of them experience symptoms of PMS, while 2 to 10 percent report severe disruption of their daily activities. Menstruation-related physical discomfort, such as dysmenorrhea, may begin with menarche. Often this condition is superseded by PMS in late adolescence or the early 20s. These syndromes generally remain stable over time.

Prevalence of PMDD

Up to 300 different premenstrual complaints have been reported in patients with PMS (Halbreich et al., 1982). Only a handful of these symptoms are consistently assessed and identified in epidemiological studies, most commonly irritability, tension, depression, bloatedness, nostalgia, and headache (Merikangas et al., 1993; Ramcharan et al., 1992; Woods et al., 1982). Epidemiological studies on the prevalence of premenstrual dysphoric disorder (PMDD) and premenstrual symptoms and syndromes have produced
mixed results, depending upon the diagnostic criteria and methodology researchers who undertook broad surveys questioning patients about general premenstrual symptoms (i.e., mood and physical symptoms) found the highest prevalence of premenstrual dysphoric patients (Spitzer et al., 2000; Singh et al., 1998). Approximately 50–80% of women will experience at least a few premenstrual symptoms that may vary from mild to severe (Wittchen et al., 2002; Hylan et al., 1999; de la Gandara & de Diego Herrero, 1996; Ramcharan et al., 1992; Woods et al., 1982). However, when more rigorous criteria are applied, the prevalence may be lower. According to the DSM-IV (American Psychiatric Association, 1994), 3–8% of women meet criteria for PMDD, a prevalence rate that has been closely replicated in several epidemiological studies and surveys (Chawla et al., 2002; Cohen et al., 2002; Wittchen et al., 2002; Angst et al., 2001; Sveindottir, Backstrom, 2000; Deuster et al., 1999; Gehlert & Hartlage, 1997; Campbell et al., 1997; Ramcharan et al., 1992; Hurt et al., 1992; Rivera-Tovar & Frank, 1990; Johnson et al., 1988; Andersch et al., 1986; Woods et al., 1982). These researches found that prevalence rates for PMDD, even when DSM-IV criteria are used, significantly vary depending upon the method of measuring symptom change. The absolute severity method in both studies produced the lowest prevalence rates in these groups 14% Hurt et al., (1992) and 1.0% Gehlert & Hartlage (1997). Robinson & Swindle (2000) compared three different assessments for PMS: global self-appraisal, summative symptom counting, and a categorical/configural approach (i.e., DSM-IV adapted) in a sample of 1022 reproductive aged women. Prevalence of significant PMS symptoms ranged from 4.9% using the global self-report, to 16.2% using the summative symptom severity measure. Although 11.3% met adapted DSM-IV criteria for PMDD, an additional 62.6% met criteria for moderate-to-severe symptoms. A strong relationship was noted between the PMDD symptom scales and social and occupational impairments. This was particularly evident with the total summative
symptom measure the more symptoms reported, the greater the interference across all life domains (Robinson & Swindle, 2000). The restrictive nature of the DSM-IV PMDD criteria, particularly the requirement of an arbitrary cutoff point of at least 5 severe symptoms, remains controversial (Freeman, 2003; Halbreich et al., 1982). A question arises as to whether women with dysphoric premenstrual syndrome are undercounted in epidemiological studies that follow DSM criteria and whether there is a substantial proportion of symptomatic women in the general population who have premenstrual impairment and distress, and may need treatment but do not meet DSM-IV criteria for PMDD due to number of symptoms reported. Chawla et al., (2002) reported that 12.6% of women met full PMDD criteria for one cycle and for the following one had lesser number of symptoms but still with high severity. Wittchen et al., (2002) found a significant prevalence (35.3%) of women with four or more premenstrual symptoms: approaching the DSM-IV's requirement of five or more yet not meeting criteria for a diagnosis of PMDD. They found an 18.6% prevalence of sub threshold PMDD. Even though the women did not meet the numerical criteria of PMDD, within the sub threshold group, a significant risk of suicide attempts (15.8%; odd ratio (OR): 5.7; 95% CI 1.8–18.3) was reported (Wittchen et al., 2002). The prevalence of premenstrual symptoms and syndromes has been found to be quite consistent in several European countries (Angst et al., 2001; Sveindottir & Backstrom, 2000; Hylan et al., 1999; de la Gandara Martin & De diego Herrero, 1996; van den Akker et al., 1995), the United States as well as China (Chau & Chang, 1998; Yu et al., 1996; Chang et al., 1995), India (Banerjee et al., 2000), and other countries (Most et al., 1981; Janiger et al., 1972). For assessments of a lifelong impact, it is of importance to note that severe premenstrual symptoms have been already reported in adolescent girls aged 14 and over (Wittchen et al., 2002; Chau & Chang, 1999; Chau & Chang, 1998; Cleckner et al., 1998; Freeman et al., 1993; Shye & Jaffe, 1991; Rivera-Tovar &
Frank, 1990). The strict 12 months prevalence of PMDD of 5.3% among adolescent girls and young women suggest that currently-cited prevalence of dysphoric PMS is overly conservative. If the arbitrary numerical requirement of the DSM IV PMDD criteria are replaced by a diagnosis based on clinical relevance, suffering, distress, and impairment (as is the case with the ACOG criteria (American College of Obstetricians and Gynecologists, 2000), the prevalence is suggested to be much higher. It is especially so if the reports of increased prevalence with aging cohorts are correct. The prevalence of clinically-significant dysphoric PMS is probably between 13% (Angst et al., 2001) and 19% (Wittchen et al., 2002; Spitzer et al., 2000).

**PMDD and anxiety disorders**

Like mood disorders, it appears that anxiety disorders occur more commonly in women with PMDD than in controls. Fava (1992) found that 59% of the women with PMDD had a concurrent anxiety disorder, with generalized anxiety disorder (GAD) being the most common. In one study of women seeking treatment at a PMS clinic with prospectively confirmed PMS, 25% had a comorbid diagnosis of GAD and 25% had a diagnosis of panic disorder (Faccinetti et al., 1992). In addition, 23% of the women had social phobia and 11% had diagnoses with obsessive-compulsive disorder. Although not explicitly stated, it appears that some women met criteria for more than one anxiety disorder. Although (Wittchen et al., 2002) did not find an increase in panic disorder in patients with PMDD compared to controls; they did find a significant increase in specific phobias (31.7% vs. 12.5%) and social phobia (21.1% vs. 6%). Alpay &Turhan (2001) in their study of general gynecology patients found a prevalence of 2% of each obsessive compulsive disorder (OCD) and generalized anxiety disorder (GAD) in patients presenting with PMDD. Pearlstein et al., (1990) found in their prescreened sample that they had to exclude 4 (4%) women due to concurrent GAD, a
diagnosis that was more common in their sample than major depression. When taking into account only the studies that gathered PMDD data prospectively, it appears that panic disorder co-occurs in 25% of these samples. Social phobia was concurrent in 19–23% and OCD in 11–13%. GAD showed the most variation, co-occurring in 4–38% of patients with PMDD. The literature on PMDD and PTSD is very limited. One study found that out of 42 women participating in a treatment study for severe PMS (prospectively assessed), 95% reported at least one sexual abuse event. Sixty-five percent were estimated to have post-traumatic stress disorder using the Crime-Related PTSD scale (Golding et al., 2000). These women were prescreened to exclude those with a depressive disorder. The method for prospective daily assessment was not discussed, although a percentage change method (30% difference between follicular and luteal phases) was used for the initial retrospective.

**PMDD and Bipolar Disorder**

The literature on PMDD and co-morbid bipolar disorder is sparse. As both disorders are cyclical mood disorders and both seem to be related to an increase in postpartum mood disorders, studying the relationship is important. In the Wittchen study (2002) of the women with PMDD, 5.7% had bipolar I disorder and 4.9% had bipolar II disorder. In the PMDD group, the odds ratio of having bipolar I or II disorder was 8 compared to those women without PMDD. Despite the fact that the PMDD data were not prospectively collected, the large number of women in this study (828 controls and 74 women with PMDD) raises the possibility that the two disorders may be more commonly concurrent than previously realized. In a sample of 180 women with bipolar I disorder, 66% reported mood changes related to their menstrual cycle (Blehar et al., 1998). Although, information about the menstrual cycle was not gathered prospectively, a striking 75% of these women reported increased mood liability, anger or irritability as their main symptoms. Only 25% reported an increase in
depression premenstrually. In 20% of these women the premenstrual symptoms were severe. A community cohort study found that 16% of women with PMS had bipolar disorder (Angst, 2001). While PMS symptoms were not assessed prospectively by daily ratings, information about premenstrual symptoms was collected at several different time points. Only one study has examined the severity of premenstrual symptoms in women with rapid-cycling bipolar disorder (RCBD), a variant requiring at least four mood episodes in one year. Price & DiMarzio (1986) found that 60% of women with RCBD had severe PMS and, using a retrospective reporting method, these same women were found to have more affective episodes per year. However, Roy-Byrne et al., (1986) presented data on 16 women with bipolar disorder suggesting there is not an increase in PMS in women with bipolar disorder compared to controls using a retrospective methodology to assess PMS symptoms. While both studies used retrospective reporting of premenstrual symptoms, two different questionnaires were used which may be one explanation for the disparity in their results. In summary, of the 5 retrospective studies that assessed bipolar disorder, the co-occurrence with PMDD varied widely from 11–60%. This wide range is partially explained by the difference that some of these studies looked for PMS in women with bipolar disorder while others looked for bipolar disorder in women with PMS. The one prospective study that reported on the frequency of bipolar disorder in women with PMDD did not find an association between the two disorders (Fava, 1992). There are case reports of patients who developed manias, which occurred exclusively premenstrually, who were responsive to lithium (DiMello et al., 1993). In a case report, a female patient diagnosed with bipolar II disorder and unresponsive to treatment with mood stabilizers and bupropion was re-diagnosed with PMDD and responded to sertraline. This response emphasized the similarity and confusion arising between the two recurrent affective cycling disorders (Macmillan & Young, 1999). Moreover, if a woman is diagnosed with bipolar disorder,
clinicians may be reluctant to prescribe antidepressants due to the potential risk of antidepressant induced mania. Two studies have found no relationship between menstrual cycles and the mood cycles of bipolar disorder. Wehr et al., (1998) did not find a relationship between the affective cycles in women with RCBD and their menstrual cycles. Although the methodology for gathering data about menstrual cycles and symptoms is not reported, it is stated that 40% of the women had affective cycles that were shorter than three weeks or longer than five weeks, making a relationship unlikely. Leibenluft et al., (1999) compared 25 women with RCBD and 25 controls using a prospective daily mood rating scale over three months. They found no relationship between mood state and severity of mood in the RCBD group based on menstrual cycle phase. However, these studies do not rule out the possibility that bipolar disorder and PMDD could exist co-morbidly or that women may experience premenstrual exacerbation of their bipolar symptoms.

Keeping in view the importance and significance of PMDD in woman daily life, the current study was designed to examine the influence of different types of treatments on PMDD.

OBJECTIVES

The study was conducted with the following objectives in view:

1. To identify the effectiveness of Yoga on premenstrual dysphoric disorder, as assessed by the Calendar of Premenstrual Experience (COPE).

2. To identify the effectiveness of CBT on premenstrual dysphoric disorder, as assessed by the Calendar of Premenstrual Experience (COPE).

3. To identify the effectiveness of fluoxetine, on premenstrual dysphoric disorder, as assessed by the Calendar of Premenstrual Experience (COPE).
4. To identify the effectiveness of the combination of YOGA and CBT on premenstrual dysphoric disorder, as assessed by the Calendar of Premenstrual Experience (COPE).

5. To identify the effectiveness of the combination of fluoxetine and CBT on premenstrual dysphoric disorder, as assessed by the Calendar of Premenstrual Experience.

**HYPOTHESIS**

The following hypotheses will be tested:

1. Yoga will be effective in reducing the intensity and the frequency of premenstrual dysphoric disorder.

2. CBT will be effective in reducing the intensity and the frequency of premenstrual dysphoric disorder.

3. Fluoxetine will be effective in reducing the intensity and the frequency of premenstrual dysphoric disorder.

4. The combination of YOGA and CBT is more effective than Yoga and CBT alone in reducing premenstrual dysphoric disorder.

5. The combination of CBT and Fluoxetine is more effective than CBT and Fluoxetine alone in reducing premenstrual dysphoric disorder.

**Sampling**

Sampling refers to the process of specifying and obtaining the participants for study. In this research, universe as the broad population to which eventual generalization of the findings is desired, includes all female married students between ages 19-30 years.

The researcher selected 120 female students out of 500 female students who have been invited for participating in an explanatory session. These 500 female students selected as a primary sample showed some signs of dysphoric mood in this session they were told: how to mark the daily symptoms report (COPE) and were asked to
return in one month time and get the second sheet for the following months. When the two (COPE) were completed in the subsequence month, screening was alone and 146 of these woman were diagnosed as having PMDD. Out of these 146 students, were selected randomly and distributed to have equal number of subjects in different groups as mentioned below:

**Comparison of six different groups during pre-test and post-test**

As mention in the description of the sample as given below this:

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**INCLUSION CRITERIA**

The inclusion criteria for the study were:

1. A woman diagnosed as a sufferer of PMDD matched with DSM-IV criteria.
2. The age range should be from 19 to 30 years.
3. To have regular menstrual cycles (21-35 days).
EXCLUSION CRITERIA

The exclusion criteria for the study were:

1. Not to be under any kind of treatment whatsoever.
2. Not to be pregnant.
3. Not to have any major psychiatric illness.

Ethical principal of this research is based on the APA rules (APA, 2000). Therefore, only those subjects who were aware of the treatment and its processes were included in this study.

Instruments:

The following instruments were used:

A: Clinical interviews based on DSM-IV-TR criteria for Premenstrual Dysphoric Disorders (PMDD).


PMDD was first described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised (DSM-III-R), then refined and included in the fourth edition (DSM-IV). (American Psychiatric Association, 1994., Diagnostic and Statistical Manual of Mental Disorders, 1987). According to the DSM-IV criteria, the diagnosis of PMDD requires a woman to have had symptoms for at least a year. Symptoms also must occur during the last week of the luteal phase and remit during the follicular phase, as confirmed by Daily Symptom Report on the Calendar (COPE). Ratings during at least two consecutive symptomatic cycles. At least one of the symptoms must be a marked dysphoric mood change, such as
depressed mood, hopelessness, anxiety, tension, anger, or irritability. Also, symptoms should not be due to exacerbations of other disorders.

The DSM-IV criteria for PMDD state that symptoms must be sufficiently serious to interfere with a woman's work, social activities, and interpersonal relationships. Signs of psychosocial impairment include marital discord, parenting difficulties, poor work performance, and increased social isolation (Mortola, 1992).

Women who only experience severe physical symptoms of PMS without accompanying mood symptoms do not meet the criteria for PMDD, even though they also may experience psychosocial impairment (Mortola, 1992).

**Daily Symptom Report on the Calendar of Premenstrual Experience (COPE):**

Several diagnostic tools have been validated for diagnosing premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD). The Calendar of Premenstrual Experiences (COPE) is a symptom calendar that allows women to rate physical and behavioral symptoms on a 4-point Likert scale. The COPE was first introduced in Mortola et al., (1999). To establish a quantitative method for the diagnosis of premenstrual syndrome (PMS), a simple prospective inventory, the calendar of premenstrual experiences, was constructed. The validity and reliability of this instrument were assessed by administering it throughout two consecutive ovulatory cycles to 36 rigidly screened women with PMS and to 18 controls. To establish concurrent validity, scores on behavioral items were correlated with simultaneously obtained scores on lengthier, well-validated psychiatric inventories designed to measure depression rather than PMS, the Beck Depression Inventory and the Profile of Mood States. The results showed that the calendar of premenstrual experiences luteal phase score distinguished PMS women from controls correctly in 104 of 108 cycles, with a 2.8% false negative
rate and no false positives when used for two consecutive cycles. An upper limit follicular phase score was observed beneath which all PMS and normal control subjects fell, suggesting that a higher score is not consistent with PMS. Correlation coefficients of calendar item scores with Profile of Mood States scale scores were 0.58 for tension, 0.51 for depression, 0.46 for anger, 0.61 for fatigue, and 0.57 for confusion (P<.0001 for all correlations). The correlation of the calendar depression item with the Beck Depression Inventory score was 0.56 (P<.0001). The test-retest reliability of the calendar given in the same phase of two consecutive menstrual cycles was high (r=0.78, P<.0001). This instrument is a valid, reliable, and practical PMS inventory, applicable to clinical and some research settings.

The COPE total scores for the luteal phase needed to exceed 41 and double the follicular phase total scores during each of the 2 consecutive menstrual cycles. In addition, the follicular phase total score could not exceed 40 and the follicular-to-luteal phase increases summed COPE ratings needed to increase by 30% for at least 5 premenstrual symptoms. The primary outcome measure in the study was the COPE (Mortola, 1992). A 22-item patient-rated scale that assesses common behavioral and physical symptoms of PMDD on a 4-point Likert severity scale. The COPE diary is a reliable instrument for identifying fluctuations in behavioral and physical symptoms during the luteal phase, and PMS symptoms can be reliably conceptualized within four factors. Symptom expression may increase in response to daily self-monitoring.

Internal consistency (a) was high (.93-.94) for the COPE total score and behavioral subscale score and moderately high (.79) for the physical subscale score. Test-retest correlations produced lower estimates of reliability (.55-.59). Four factors, accounting for 64% of the total variance, were extracted: mood symptoms, somatic/cognitive symptoms, appetitive symptoms and fluid retention
symptoms. Symptom reports increased in consecutive luteal phases for three of the four factors; however, the factor structure remained consistent in consecutive months. The cope diary is a reliable instrument for identifying fluctuations in behavioral and physical symptoms during the luteal phase, and PMS symptoms can be reliably conceptualized within four factors (Feuerstine & Shaw, 2002).

The PMDD criteria of the DSM-IV requires the presence of 5 out of 11 symptoms to make the diagnosis of PMDD. The eleven symptoms are as follows:

1) At least 1 of the first 4 symptoms must occur during the last week of the luteal phase, begin to remit within a few days of the onset of menstrual flow, and be absent in the week after menses.

2) The symptoms must be severe enough to interfere with social, occupational, sexual, or scholastic functioning. Symptoms must be discretely related to the menstrual cycle and must not merely be a worsening of preexisting depression, anxiety, or personality disorder.

3) All of the above criteria must be confirmed prospectively by daily ratings of at least 2 consecutive menstrual cycles. The diagnosis may be made provisionally before this confirmation.

Of the symptoms listed in the DSM-IV, 10 of 11 are emotional and behavioral in nature. Only one includes multiple common physical symptoms. As such, PMDD defines a narrow group of women with the most severe premenstrual emotional symptoms, with functional impairment, and without a concurrent axis I or axis II disorder that is exacerbated premenstrually. Women who meet the PMDD criteria are coded on axis I as depressive disorder not otherwise specified. Obviously, this criterion excludes many women presenting with predominantly physical premenstrual symptoms and women with premenstrual exacerbation of underlying axis I or II 

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disorders. Interestingly, DSM-IV criteria state that PMDD may be superimposed on axis I or II disorders. However, how to differentiate between exacerbation of and superimposition on symptoms of an axis I or II disorder is unclear.

Several scoring systems are available for symptom quantification. A recent suggestion is that a within-cycle increase from follicular to luteal phase score (demonstrating "on-offness") of at least 50% is necessary to confirm the diagnosis of PMDD and to merit psychopharmacologic intervention. The within-cycle percentage change is calculated by subtracting the follicular score from the luteal score, divided by the luteal score, and multiplied by 100.

(\text{luteal} - \text{follicular} / \text{luteal}) \times 100.

More than 60 instruments have been used for symptom recording. A 24-item form called the Daily Record of Severity of Problems incorporates all DSM-IV symptoms of PMDD. As one may expect from this large number of instruments, a review of scoring methods used in most studies failed to identify a uniquely favorable method (Thwe, 2006).

The Data analysis

The data were analysed by making use of t-test of significance. Process variable, will be examined using measures by applying the SPSS, version16. The research plan, as an experimental plan, included CBT, Fluoxetine, Yoga, CBT&Yoga; Fluoxetine& CBT.

It has been suggested that cognitive attribution may be important in the etiology of PMS dysphoria, Ussher, (1992). The cognitive approach to somatic symptoms, (Salkovskis,1989) is promising in that it provides a framework for considering both psychological and physical factors. This type of cognitive model is similar to the approach that has been applied successfully to the understanding and treatment of a range of “psychosomatic” problems
such as panic (Salkovskis & Clark, 1991; Clark, 1986) and hypochondriasis (Salkovskis, 1997).

The current study evaluated the influence of different types of intervention strategies in the context of PMDD. Although, Cognitive - Behavior Therapy, Yoga Therapy, Pharmacotherapy were effecting ideally with the treatment of PMDD. In isolation, the study found that the combination that Cognitive - Behavior Therapy and Yoga Therapy is more effective than these therapies in isolation. The utility of Fluoxetine in isolation is relatively doubtful in comparison to effectiveness of cognitive behavior therapy and yoga therapy. The role of Fluoxetine is slightly beneficial in combination to cognitive behavior therapy. All this suggests that cognitive behavior therapy is a key therapy for the treatment of PMDD, the effect of cognitive behavior therapy becomes more pronounced, when used in combination with yoga therapy. Needless to say the impact and utility of yoga therapy and cognitive behavior therapy have been explained in the early pages.