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Identification and Assessment of Pre-menstrual Symptoms and Syndromes in Women - An Epidemiological approach to the Investigation

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Abstract

Lack of systematic data from India regarding an important aspect of women's mental and reproductive health necessitates an in depth evaluation and assessment of this area. This paper discusses methodological issues in assessing problems and prevalence of pre-menstrual symptoms and syndromes in a group of Indian women. The target population of 2400 women was systematically assessed towards the presence of different symptoms occurring in the Pre-menstrual period. The various features for study were related to mood, cognition, physical symptoms and behaviour. An assessment was also made of the disability women faced because of this problem. The proportional division of the 2400, women was drawn on a stratified sampling basis with representation for urban and rural groups in a 2:1 ratio. The selection of the sample provided adequate representation for instruments, training of field investigators and establishment of quality control formed other key components of the study. This paper also reviews the various epidemiological studies done in the area and discusses in detail the methodological aspects of this epidemiological study.

Key words -
Pre-menstrual syndrome,
Epidemiology,
Women

The pre-menstrual syndrome (PMS) has often been described as a heterogeneous disorder [1], [2]. The heterogeneity mainly relating to the diverse ways in which it presents, the combination of various experiences and the differences found in various population groups, because of the confusion and methodologic imprecision that characterises the literature, three conclusions have emerged. First, careful analysis of women suffering from PMS has revealed the existence of several overlapping syndromes rather than a single syndrome. Second, in addition to specifying the types of symptoms observed, the description should' include both the quantitative and qualitative aspects of experience, and finally, confirmation of the syndrome by methods; such as prospective rating is a must [3].

A number of epidemiological studies have attempted to look at this clinical entity, Table I depicts the major studies done by various groups of workers in recent years and the different methods and samples used. These studies differ in their prevalence rates for probably six reasons.

Table I - Summary of the important epidemiological studies on PMS in the last decade

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1. The nature of the sample studied has been different in each of these studies have used hospital popula [2] except a few on college students [3] and military wives [4]. Some have used a younger group of college women [3] and military wives [4]. Some have used a younger group of college women [3] while others have focussed on normal volunteers [5] or a general practice sample [6]. It is known that age, occupation and other family or personal variables can influence pre-menstrual symptoms.
2. The sample size has also varied from 50 [2] to 950 [7]. Smaller samples specially in a disorder like PMS, influenced by individual and socio-demographic variables does not allow for wider comparison and generalisation.
3. The nature of assessment has differed in most of these studies. Some have measured merely the prese [7] while others have attempted a quantitative assessment [4], [9]. The number of symptoms studied has varied from 19 [9] to 95 [4]. Most studies have focussed on distressful or negative symptoms [3], [4], [5] while some of the more recent ones have assessed the presence of positive [8] and mixed or biphasic changes [11].
4. The studies have been retrospective or prospective in nature with only one study using a combination [2]. Hence the studies focus on only one component and are non confirmatory in nature.
5. Recent studies [13], [14] have differentiated symptom occurrence from symptom exacerbation [4], [5] and have also used prospective confirmation of symptoms reported retrospectively.
6. Finally, the criteria, for definition of PMS have varied. Some have used the NIMH criteria [4] while others have diagnosed the condition by current diagnostic systems namely the DSM-III R criteria for Late Luteal Phase Dysphoric Disorder [16].

It can be summarised from the above description that there is indeed a great deal of heterogenity in the nature of the studies which might be one possible reason for the lack of systematic data and for varying prevalence rates. It was for all the above reasons that it was thought necessary that a community based study of an epidemiological nature should be undertaken in order to detect the true prevalence of this so-called western culture bound syndrome [17].

It has been attempted to keep in mind all the methodological limitations of previous studies and overcome them. Several factors were considered, such as encompassing a large number of women drawn from different stratified sections representing various geographical areas, belonging to different age groups and inclusion of both working and non working women. In order to circumvent some of the limitations of the previous studies, both the intensity and presence of different symptoms were proposed to be studied as also the differences between symptom occurrence and symptom exacerbation. Also, both prospective and retrospective methods were planned including longitudinal confirmations of probable positive cases. It is hoped that with these methodological improvements we will have a more realistic appraisal of this syndrome in Indian women. The subsequent part of this paper describes in detail the plan and methodology of this study which was undertaken between October 1991 and January 1993.

Sample size

The sample size was determined using standard statistical procedures [15]. A simple formula viz.. Z=d/pq/n was used to calculate the sample size. The calculations permit the estimation of sample size by keeping precision limits, safety factor and approximate idea of population values through available information. As per the accepted methods p=prevalence of the condition, q=1 - p, n=sample size, d=sampling error and z=accepted variation limits, were considered to arrive at the required sample size. Based on this a sample size of 2170 subjects was considered for the study and keeping 10% extra subjects for attrition, the total sample required was 2400.

Study areas

An important aspect of this study was to assess women from different strata of society and of different age groups and occupations. In order to get an adequate representation of women from in and around Bangalore it was decided to recruit into the study, women in the age group of 15-45 years from urban and rural areas. Women were included from a middle class locality (Shanthinagar) and a village (Bidarguppe) respectively.

Selection of subjects

In view of the special focus of age, education and occupation on pre-menstrual experience the sample was identified by stratified methods to give adequate representation for all the groups. The total sample was further classified into two groups for urban and rural population and was in the ratio of 2:1. The urban subjects were identified from 3 groups. These three groups were

(i) urban collegiate students
(ii) working women and
(iii) non-working house wives.

The proportional representation of these groups were 800, 400 and 400 respectively. A list of all colleges was drawn up which included government, private, professional and evening colleges. Through a process of randomisation colleges were chosen and consent was obtained from the concerned authorities. Fourteen colleges were thus selected. The selection of urban working women was made similarly by a random method to include 14 industrial establishments, banks and offices. The urban locality to identify housewives was done by the selection of a residential locality. The local census maps and information was obtained from the Directorate of Census operations. From the total enumeration blocks a list of women population in respective blocks was made. 5% of blocks were chosen by a random method and a house to house survey was conducted. Only those women who were residents of Bangalore for at least 6 months and who could communicate in the local language were included. The rural area selected was a group of villages which had all the characteristics of a rural area and the women were included from households by serial numbering.

Inclusion and exclusion criteria

The inclusion criteria for the project were:
- Women in the reproductive age group of 15-45 years
- Period of residence for the urban and rural group being for at least 6 months.
- Women who had been having menstrual periods in the last 6 months.

Exclusion criteria were:
- Presence of major gynaecological illness in the last 1 year
- Presence of severe and acute physical illness such as anemia, malignancy, chronic infections, etc.
- Moderate or severe mental retardation

Definitions

The following definitions were used for the purpose of the study:
- Pre-menstrual period - Five days before the onset of period
- Last menstrual period - The first day of the menstrual period which occurred most recently.
- Pre-menstrual syndrome - Cases fulfilling criteria for Late Luteal Phase Dysphoric Disorder as per DS [4].

Prestudy activity

Before embarking on the study certain activities were taken up. These consisted of finalization of instruments and training of the research workers in the use of these. The instruments used had already been factor analysed in a different population [12]. Minor changes in language were made based on the observations of the research staff.

A pilot study was undertaken for the above purpose in which a local area near the hospital was selected. The research staff familiarised themselves with the instruments and were trained in the art of interviewing women regarding their beliefs and experiences related to the reproductive system. During this phase an inter-rater and test-retest reliability exercise was conducted which confirmed the reliable nature of the data gathered. The linguistic competence of the research workers was enhanced, specially in relation to discussion of menstrual and pre-menstrual issues. The two research workers (field investigators) were also trained in detecting historically the presence of gynaecological and physical illnesses in women which also ensured the correct application of the criteria for inclusion and exclusion.

Study instruments

Five instruments were used for the purpose of the study:

a)Pre-menstrual Assessment Form I

This was a 20 item form which assessed cross-sectionally how the woman felt on the day of assessment. The respondent had to rate her feelings and experiences on a scale of 0 to 100. The form

has the advantage of getting an unbiased rating on these items as it does not mention anywhere its relation to the menstrual cycle. The details of menstrual periods and the date of the last menstrual periods and the data of the last menstrual period is calculated based on questions at the end of the form pertaining to a woman's general health.

b)Pre-menstrual Assessment Form II

This form has 57 items and assesses the presence of various emotions and experiences which can possibly occur in relation to the pre-menstrual period. A list of these experiences was made by an exhaustive literature search. The women had to rate the presence or absence of each item during their pre-menstrual phase. When present, the severity, continuity and disability due to these experiences was assessed in the final section of the form. The items in this form related to mood, cognition, physical and biological changes.

c)Pre-menstrual Assessment Form III

This is a 17 item form which retrospectively rates the presence and severity of various pre-menstrual experiences on a scale of 0 to 100 . The scale has the advantage of also measuring these changes in the rest of the cycle, to enable detection of extent and nature of change and elimination of false positive cases which would be included if a 'rest of the cycle' rating was not included. The extent of interference during the pre-menstrual phase with work, social activities and interpersonal relationships is also assessed on as scale of 0 to 3 at the end of the form.

d)Prospective Assessment Form

This form was specially designed to prospectively assess changes over the various menstrual phases of important experiences and emotions. The form has a cross-sectional method of rating i.e., it rates feelings and experiences of that day and has the advantage of unbiased ratings. Both numerical and visual analogue methods of ratings were used.

e)The Comprehensive Form

During the prestudy phase it was felt that women who could not read or who id not have enough time to respond to the above questionnaires needed a shorter version which was incisive and precise without excluding the key items of the other forms. For this, a shorter form - the comprehensive version was constructed. This takes about 10 minutes for administration and rating.

All the above instruments were designed specifically for the project and had been used in other populations to establish their reliability and validity. All these were standardized and all personnel involved were trained to achieve a high degree of uniformity.

Methods of the Study

Two field investigators with qualifications in psychology & social work were involved in data collection. Consent was obtained prior to administering the tools from the administrative authorities of various colleges, industrial establishments and offices. Informed consent was also obtained individually from every respondent.

All the women included in the study were administered at least two of ;the forms and, wherever possible all these forms were used. In case of illiterate women the data collection was done by reading

out the items and noting the responses, and in some cases the comprehensive form was used.

Prospecitve study

Women form a nearby college underwent weekly prospective assessment over three months.

All the data collection was carried out in the field i.e., in various colleges, industries, door to door survey in urban areas and the rural areas. Data for all the women was collected and the details coded for analysis.

Quality control

Frequent visits by the investigators to the field with the research workers ensured that the data collection was done appropriately which included supervision regarding explanation of the study, rating methods and linguistic difficulties.

In a number of cases specific checks were done regarding exclusion and inclusion criteria and concurrent psychiatric morbidity.

Specific issues in methodology and conduct of the study

Being a large scale study the data collection required substantial organisational effort. It also required a certain sensitivity to women's health problems as we were enquiring into extremely personal and intimate details. Most women had a number of questions to ask about menstruation and pre-menstrual distress which had to be handled usually by a discussion or a lecture at the end of data collection (in order to avoid bias before rating). Wherever necessary, the investigators had to be called in for consultations in case a concurrent gynaecological or medical illness was detected. However, majority of women were extremely cooperative and honest about their responses and were very often glad that these questions had been asked and their doubts and worries cleared.

Despite considering and circumventing many of the methodological issues in PMS research, the study does have a few lacunae. These are mainly related to:

1) Questionnaires being structured and not open ended which might lead to biases in reporting specially when exploring a new area of human behaviour.
2) Issues related to co-morbidity of psychiatric and medical illnesses with PMS could not be assessed in detail.
3) Absence of daily rating for prospective assessment.
4) Personality variables and marital/family issues were not evaluated.

An attempt will however be made to overcome these shortcomings by detailed assessment on the above parameters of all those women identified as PMS positive.

Analysis

The data analysis would delineate and identify various symptoms of this clinical condition. The prevalence of the condition will be determined and an attempt made to identify those women with a severe PMS, which interferes with their social, personal and occupational functioning. PMS will be defined by two criteria - namely the DSM 3 R proposed category of Late Luteal Phase Dysphoric disorder and the NIMH criteria [4]. We also plan to use cluster analysis in order to derive at the possible profiles and subsyndromes and also to study associations of the various clinical syndromes with sociodemographic and gynaecological factors.

All the women identified as suffering from severe PMS need to be contracted by mail and attempts made to have detailed interviews. In order to detect false positivity, along with the interviews, the women will be asked to maintain prospective ratings for two menstrual cycles. Once confirmed, the woman will be designated as having a PMS. We also hope to delineate risk factors that predispose a woman to develop PMS and attempts will be made to detect co-morbidity given its strong association with affective disorder [18].

We hope that the study will help us in unravelling the true nature and prevalence of this otherwise 'hidden' illness in Indian women.

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