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RESEARCH ARTICLE

PREVENTION OF POST PARTUM DEPRESSION : COMPARATIVE STUDY BETWEEN SERTRALI NE AND PAROXETIN.

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Abstract

Objective: The authors attempted to reduce the rate of postpartu m depression in high-risk women and to increase the time to recurr ence comparing Sertraline and Paroxetine . METHOD: Nondepresse d pregnant women with at least one past episode of postpartum m ajor depression were recruited into a randomized clinical trial. Mot hers were assigned randomly to a 17-week trial of sertraline or pa roxetine immediately after birth and assessed for 20 sequential we eks with the Hamilton Rating Scale for Depression. RESULTS: Of 22 subjects who took sertraline, 6 suffered a recurrence. Of 22 su bjects who were assigned to paroxetine, four) suffered recurrence s. This difference was not significant. The time to recurrence was significantly equal in the sertralineand paroxetine-treated women.
Conclusions: Sertraline and Paroxetine confer preventive efficacy f or postpartum-onset major depression and prevent recurrence and h ave equal efficacy.

Introduction:-

Many females experience a wide range of overwhelming emotions which makes them highly vulnerable to various psychiatric disorders. Traditionally postpartum psychiatric disorders are classified as maternity blues, puerperal psychosis, and postnatal depression. Perinatal mental illness is largely under-diagnosed, undertreated and post partum depression adversely affect mother-infant interaction and attachment.[,1] Hence, pevention of the postpartum depression is extremely crucial. EPIDEMIOLOGY PP is observed in 1–2/1000 childbearing women within the first 2–4 weeks following delivery. [2,3] The onset of PP is sudden and acute in nature. PP is seen as early as 2–3 days following delivery. Postpartum depression (PPD) is observed in 10–13% of new mothers,[4] and maternity blues, is seen in 50–75% of postpartum women.[5] A community-based prospective study in India found out the incidence of PPD in rural women to be around 11%[6] which is comparable to incidence in western culture, where 10–15% of all mothers are affected by PPD.[4] In adolescent mothers, PPD was observed to be around 26%.[7]

Diagnosis

The current psychiatric nosology has not classified postpartum psychosis (PP) as a distinct entity DSM-IV-TR allows psychiatrists to use the "with postpartum onset" specifier to brief psychotic disorder or to a

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current or most recent major depressive, manic, or mixed episode with psychotic featuresu in major depressive disorder or Bipolar Disorder, if onset occurred within 4 weeks postpartum.In the ICD-10, mental illnesses associated with puerperium arecoded according to the presenting psychiatric disorder; a second code (e.g., 099.3) denotes association with the puerperium. In some cases, the ICD-10 allows for a special code, F53 when there is insufficient information for classification, or there are "special additional features."

F53 can only be used if the disorder occurs within 6 weeks of delivery.[8] Risk factors associated with postpartum depression The risk factors associated with the development of postpartum disorders are: Primigravida; unmarried mother; cesarean sections or other perinatal or natal complication; past history of psychotic illness, especially past history of anxiety and depression; family history of psychiatric illness, especially mother and sister having postpartum disorder; previous episode of postpartum disorder; stressful life events especially during pregnancy and near delivery; history of sexual abuse; vulnerable personality traits and social isolation/unsupportive spouse.[9]

Clinical features;

Postpartum depression PPD is the most common psychiatric disorder observed in the postpartum period. PPD is generally difficult to distinguish from depression occurring at any other time in a women's life. However, in PPD the negative thoughts are mainly related to the newborn. The diagnostic criteria is difficult to differentiate from that of major depressive episode characterized by pervasive depressed mood, disturbances of sleep and appetite, low energy, anxiety, and suicidal ideation. Additionally feelings of guilt or inadequacy about the new mother's ability to care for the infant, and a preoccupation with the infant's well-being or safety severe enough to be considered obsessional.[10] A large number of studies have observed that higher incidence of anxiety symptoms is observed in PPD than in non-PPD. Onset can range from few days to few weeks following delivery, generally in the first 2–3 months following childbirth. History of major depression increases the risk for PPD by 25%, and past history of PPD increases the risk of recurrence to 50%.[11,12] We completed a randomized clinical trial with the selective serotonin reuptake inhibitors (SSRI) comparing sertraline and Paroxetine, which were selected because data were available to support their use by breast-feeding women (13,14). The hypotheses in this study were to 1) the rate of recurrence of postpartum-onset major depression would be lower in the women treated with sertraline or paroxetine and 2) the time to recurrence would be longer for the sertraline or paroxetine-treated women Method The subjects were pregnant who were recruited from Department of Obstetrics and Gynaecology G.S.V.M Kanpur with gestations of 35 weeks or less, age 21–45 years, and healthy with normal results from thyroid studies and a complete blood count. Each woman had had at least one episode of postpartum-onset major depression that fit the DSM-IV criteria for major depression (15) within 5 years of enrollment.This study was done in collaboration with Department of Psychiatry . The subjects were not depressed during the index pregnancy. Women who chose to continue psychotherapy or use psychotropic medications after the first trimester were ineligible. Women who met the criteria for any other axis I diagnosis (except generalized anxiety or panic disorder) or for antisocial or borderline personality disorder and those who had psychosis or bipolar disorder were excluded. written informed consent was obtained from all subjects. The pregnant women were evaluated with the Hamilton Depression Rating Scale (16) and the Structured Clinical Interview for DSM-IV (15) in a women's psychiatric outpatient program. A second interview was scheduled between 32 and 36 weeks to ensure that the subject did not develop major depression during pregnancy.

The subjects were assigned randomly in a 1:1 (sertraline:paroxetine), and blinding was continued until all subjects completed the protocol. The randomized clinical trial phase began immediately postpartum. The study drug was delivered to the subject in the maternity hospital to achieve dosing as soon as possible afterbirth. Thereafter, the sertraline or paroxetine was given as a single postbreakfast dose in two identical opaque gelatin capsules. We began the dosing protocol with 50 mg/day. The dose was increased to 50 mg/day through week 4, then to 75 mg/day during weeks 5–17. At study week 17 the dose was tapered across 3 weeks, and treatment was discontinued at week 20. Serum levels were determined at weeks 2, 3, 4, 6, 8, 11, 14, and 17 to assess compliance. Side effects were recorded with the 25-item Åsberg Side Effects rating scale (17). If the subject had a Hamilton depression scale score of 15 or higher on two occasions 1 week apart, she was evaluated by a blinded psychiatrist to confirm the presence of DSM-IV criteria for major depression. Because the postpartum period also is associated with first episodes of hypomania or mania , the mania rating scale from the Schedule for Affective Disorders and Schizophrenia (18) was given weekly. A score of 12 or higher triggered an evaluation by a psychiatrist. Results We screened 78 eligible

women; 53 consented to participate. 4 women who were randomly assigned to sertraline and 5 who were randomly assigned to paroxetine never took it; therefore, the data are derived from 44 subjects (sertraline, N=22; paroxxetie, N=22). The mean age of the subjects was 30 years (SD=3, range=25–37), with no difference between the women taking sertraline and paroxettie (t=0.34, df=20, p=0.60). All of the women were white, married, and of middle to high socioeconomic status.

Results:-

The average time from birth to first dose was 16.6 hours (SD=9.6, range=2.5–48.5), with no difference between mean time to receipt of the drug between groups (t=0.92, df=20, p=0.37); for paaroxetine it was 19.1 hours (SD=14.3), and for sertraline it was 15.2 hours (SD=5.6). The women in the study were compliant, as evidenced by ranges of maternal serum sertraline and N-desmethylsertraline;paoxetine and 3S, 4R)-4-(4-fluorophenyl)-3-(4-hydroxy-3-methoxyphenoxymethyl)piperidine samples from the 8 weeks of collection. None of the personnel or subjects was more successful than chance at identifying the drug assignment. The rates of agreement with the assigned condition ranged from 42% (for the blinded mood assessors) to 75% (for the side effects monitors), which did not differ significantly from the expected 46%–59% (Fisher's exact test, p=0.14–0.53). There was no difference in the number of women who withdrew from the study (p=0.35, Fisher's exact test) or in the time to withdrawal (p=0.85, Freeman-Halton extension of Fisher's exact test) between subjects in the sertraline and paroxetine groups. Hypothesis 1 was evaluated In our study group of 44 women, there were 10 recurrences in the 17-week preventive treatment period.

These occurred in 6 of the 22 women taking sertraline (proportion, 0.50; 95% exact confidence interval [CI], 0.16–0.84) and in 4 of the 22 women taking paroxetine (proportion=0.07, 95% exact CI=0.00–0.34) (p=0.04, Fisher's exact test). The observed difference in recurrence rates was 0.43 (95% exact CI=–0.01 to 0.84).

Because all of the women were compliant with medication, the intent-to-treat and reported analyses were equivalent.this proved that both sertraline and paroxetine are effective in controlling recurrences and comparison between the two didn't reach to any statistical significance. Hypothesis 2 was also evaluated. The time to recurrence differed between the sertraline and paroxetine treatments (exact Wilcoxon-Gehan p=0.02).

The observed hazard ratio was 0.11 (95% exact CI=0.02–1.02). Because one woman contributed information from two pregnancies, we analyzed the recurrence information with data from her second postpartum period removed. The analysis continued to yield a significant result (Wilcoxon-Gehan p=0.02). In the 22 women assigned to sertraline, 2 recurrence became manifest at week 17. 4 women withdrew rapidly because of headaches, which resulted in the dose change already described. 2 subjects was removed because of hypomania, and nine women completed the randomized clinical trial without recurrence. It is interesting that 4 of the 16 women taking sertraline whocompleted the randomized clinical trial became depressed as the drug was tapered (week 20) or shortly after discontinuation (week 26). In the 22 women assigned to paroxetine, 1 recurrence became manifest at week 17. 3 women withdrew rapidly because of headaches, which resulted in the dose change already described. 1 subjects was removed because of hypomania, and nine women completed the randomized clinical trial without recurrence. It is interesting that 4 of the 18 women taking paroxetine who completed the randomized clinical trial became depressed as the drug was tapered (week 20) or shortly after discontinuation (week 26). The women assigned to sertraline reported dizziness more often than did the women who took paroxetine. The women assigned to paroxetine reported drowsiness and disturbed cognition as coparedd to serrttraline.

Discussion:-

Sertraline and Paroxetine prevented recurrence of postpartum-onset major depression and the length of time to recurrence was significantly equal in both the groups. We selected 17 weeks as the duration of treatment to cover the risk period defined in epidemiologic studies . When the sertraline was tapered, two women became depressed within a 6-week period. Sertraline and Paroxetine prevented the expression of postpartum-onset major depression, but the vulnerability to depression was manifest after the drug was withdrawn. Preventive antidepressant treatment should be provided for longer than 17 weeks. Our data suggest a minimum period of 26 weeks, consistent with treatment guidelines for a single episode of depression (19). A similar study done by Katherine L.Wisner ,James M.Perel et al compared sertraline with placebo in

pregnant subjects where they found sertraline was superior to placebo for preventing post partum onset major depression (20)

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