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IMPACT OF PATIENT COUNSELING AND MEDICATION ADHERENCE IN POSTPARTUM DEPRESSION PATIENTS: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract: Postpartum depression (PPD) is a complex combination of physical, emotional, and behavioral changes that happens in most of the women after giving child birth. The present study was to compare the effectiveness before and after patient counselling with medication adherence in postpartum depression patients. A prospective comparative study method was used to determine the impact of patient counselling and to evaluate the prevalence of risk factors in PPD patients. Pill count method was used to estimate the adherence of the medication before and after patient counselling. Three sessions of patient counseling were conducted by using Edinburgh postnatal depression and RCOG scale whereas medication adherence was estimated using modified morisky scale. For each session a comparison was done before and after patient counselling to know the medication adherence and its impact which was evaluated based on disease improvement status. From the study it was found that prevalence of PPD rate was 98.66% and the most affected age group is 18 to 24 years. Among the risk factors, abortion is the most prevailing risk factor and married women were mostly affected. During the first session of counselling it was found that the medication adherence was 22% and increased significantly after each follow up counselling and 100% medical adherence was found during the third session. From the study we concluded that patient counseling had a significant impact which helped in improving quality of life in PPD patients and reduces complications such as affected bond between mother and baby, family members and social communication.

IndexTerms **– Postpartum depression, Medication adherence, Patient counselling.**

I. INTRODUCTION

The term postpartum depression commonly includes major and minor depression which differs in severity and prognosis and has a combined incidence of 7to 15% in the first three months postpartum. The overall incidence of 5 to 7% in the first three months suggesting the postpartum women have major rates of depression in general population [1].

Postpartum depression is complex combination of physical, emotional, and behavioral changes that happened in some women after giving child birth. Postpartum depression occurs in women after they carried a child usually in first 4 to 6 months. It can last for longer than 3 months and even years if not treated. For most women, having a baby is a very exciting, joyous, and often anxious time. But for women with postpartum depression, it can become very distressing and difficult. The use of the term postpartum recognizes that depression associated with having a baby often begins during pregnancy [2].

Postpartum depression is a significant, but treatable medical condition characterized by intense sadness, indifference, and anxiety, as well as changes in energy, sleep, and food. It poses dangers to both the mother and the baby. Postpartum depression affects one out of every seven women. Women are especially vulnerable during pregnancy and the postpartum period. Biological, emotional, economical, and social changes are common for mothers during this time. Some women are at a higher risk of having mental health issues, especially despair and anxiety.

1.1 Aetiology:

The etiology and pathogenesis of PPD remains unclear. Some women may be sensitive to hormonal changes during reproductive events, specifically menses, pregnancy, and menopause. The drop in hormone levels after delivery may play a role. An association between cortisol levels and depressive symptoms during pregnancy and continue in to postpartum period. PPD is caused by biological (genetic, neurological, and hormonal) and psychosocial (stressor) components, as well as their combination (e.g.: epigenetic). PPD is distinct in terms of its onset (after birth), psychosocial stressors (e.g., parenting a new infant, relationship transitions), and physiological basis (the dramatic rise of gonadal hormones followed by fast withdrawal associated with pregnancy and birth, respectively) [3, 4].

1.1.1 Psychosocial factors: Psychosocial factors such as perceived stress (e.g., feeling overwhelmed) and chronic strain (e.g., financial stress, job insecurity or flexibility) have been linked to PPD. Low social support has been linked to PPD.

Childbirth and newborn care are psychosocial stressors that occur most frequently during the postpartum period. Unplanned or unwanted pregnancy has a minor effect size, while childcare stress and baby temperament have moderate to large effect sizes. PPD risk is also influenced by the method of delivering. When compared to vaginal delivery, having a caesarean section increases the risk of PPD. Parenting stress at 6 weeks after delivery was linked to PPD at 3-6 months after delivery [5, 6].

1.1.2 Genetic factors: Most research indicates that PPD may cause by genetic factors. Genes involved in reproductive and stress hormone pathways ex: estrogen and glucocorticoid receptor genes. Overall PPD share 2/3 rd of a genetic variance [7].

1.1.3 Neural factors: Some of the PPD-related brain areas PPD are associated with decreased activation in brain regions such as the ventral striatum. Neurotransmitter systems such as the serotogenic and GAMA amino butyric acid systems have been linked to PPD [8].

1.2 Signs and Symptoms:

Symptoms of postpartum depression may differ from non-postpartum depression [9]. In general, the symptoms of PPD include severe changes in sleeping, eating, and activity patterns. Many women with postpartum depression have no psychiatric history and may be reluctant to volunteer symptoms or to seek help Symptoms of postpartum depression can be hard to detect [10]. Many women have these symptoms:

Inability to sleep or sleeping a lot, when a baby is awake, mood swings, change in appetite, fear of harming, extreme concern and worry about baby, sadness or excessive crying, feeling of doubt, guilt and helplessness, difficulty concentrating and remembering, loss of interest in hobbies and usual activities, recurrent thoughts of death, which may include thinking about or even planning suicide

1.3 Diagnosis:

PPD symptoms are similar to depression symptoms that begin after the postnatal period, according to the Diagnostic and Statistical Manual-IV (DSM-IV). Loss of interest or pleasure (anhedonia), low mood, exhaustion, poor focus, feelings of worthlessness or excessive guilt, psychomotor retardation, suicidal thoughts, hunger, and sleep disturbance are some of the symptoms.

A person must have at least 5 of these 9 symptoms, including loss of pleasure or a depressed mood, to be diagnosed with severe depression. The onset of symptoms within four weeks of birth is considered an episode of PPD, although the International Classification of Diseases-10(ICD-10) considers onset within six weeks. According to some other manuals or classifications, PPD is defined as the first six months after delivery or the entire postpartum year [11, 12, 13, 14].

1.3.1 Assessment scales:

There are two different scale used widely to assess the severity of PPD. They are

Edinburgh postnatal depression scale (EPDS).

Beck depression inventory(BDI)

EPDS:

EPDS is a ten-question scale that the mother fills out to assess depression symptoms in a simple language that is easy to comprehend and explain in a scoring mechanism. It also accessible in nearly 50 languages, and it usually takes less than 5 minutes to complete. The patient is asked to respond depending on their feelings during the previous seven days. A score of 30 or more suggests severe depression, whereas a score of 30 or less indicates mild to moderate symptoms (See fig:1).

BDI:

BDI is another assessment scale that contains 20 questions and takes longer time to complete and score when compared to EPDS. This scale instructs the patient to answer the questions based on their feelings within last two weeks. The score greater than sixty three considered as more severe depression [15].

Edinburgh Postnatal Depression Scale[1] (EPDS)

Name: Address:

Your Date of Birth:

Baby's Date of Birth: Phone:

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

Here is an example, already completed.

I have felt happy:
- Yes, all the time
- Yes, most of the time — This would mean: "I have felt happy most of the time" during the past week.
- No, not very often — Please complete the other questions in the same way.
- No, not at all

In the past 7 days:

1. I have been able to laugh and see the funny side of things
   - As much as I always could
   - Not quite so much now
   - Definitely not so much now
   - Not at all
2. I have looked forward with enjoyment to things
   - As much as I ever did
   - Rather less than I used to
   - Definitely less than I used to
   - Hardly at all
3. I have blamed myself unnecessarily when things went wrong
   - Yes, most of the time
   - Yes, some of the time
   - Not very often
   - No, never
4. I have been anxious or worried for no good reason
   - No, not at all
   - Hardly ever
   - Yes, sometimes
   - Yes, very often
5. I have felt scared or panicky for no very good reason
   - Yes, quite a lot
   - Yes, sometimes
   - No, not much
   - No, not at all
6. Things have been getting on top of me
   - Yes, most of the time I haven't been able to cope at all
   - Yes, sometimes I haven't been coping as well as usual
   - No, most of the time I have coped quite well
   - No, I have been coping as well as ever
7. I have been so unhappy that I have had difficulty sleeping
   - Yes, most of the time
   - Yes, sometimes
   - Not very often
   - No, not at all
8. I have felt sad or miserable
   - Yes, most of the time
   - Yes, quite often
   - Not very often
   - No, not at all
9. I have been so unhappy that I have been crying
   - Yes, most of the time
   - Yes, quite often
   - Only occasionally
   - No, never
10. The thought of harming myself has occurred to me
    - Yes, quite often
    - Sometimes
    - Hardly ever
    - Never

Administered/Reviewed by: Date

[1]Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10 item Edinburgh Postnatal Depression Scale. British Journal of Psychiatry 150:782-786.

[1]Source: K. L. Wisner, B. L. Parry, C. M. Piontek, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002; 194-199

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Figure 1: Edinburgh postnatal depression scale

1.4 Treatment:

1.4.1 Pharmacological therapy:

Pharmacologic management can be utilized in conjunction with cognitive based therapy for patients who refuse to attend therapy with a mental health practitioner or who have previously proven benefit from pharmacologic intervention. In the postpartum period, the use of selective serotonin reuptake inhibitors (SSRIs) is allowed, and this class of drug has been shown to give statistically significant improvement in PPD symptoms [16, 17]

PPD is most typically treated with selective serotonin reuptake inhibitors (SSRIs), serotonin-nor epinephrine reuptake inhibitors (SNRIs), and tricyclic antidepressants. Monoamine oxidase inhibitors (MAOIs) are not suggested since they have been linked to an increase in blood pressure, and their interactions with food and other drugs can make therapy more difficult (23,24).

If a patient receiving an SSRI does not experience remission from depression symptoms or has only minor side effects, the provider may choose to switch the patient to another SSRI or to an SNRI. Desvenlafaxine, duloxetine, and venflaxine are the most widely prescribed SNRIs. In PPD breastfeeding mothers, SNRIs are not indicated as a first-line treatment.

Brexanolone was recently approved by the FDA for the treatment of PPD. Brexanolone is derived from allopregnanolone, a GABAA receptor allosteric modulator. Endogenous allopregnanolone levels drop rapidly after delivery, which I believe contributes to PPD. Brexanolone, has been shown to be effective in treating depression in a variety of postpartum mothers. The medicine is administered intravenously over a 60-hour period, with symptoms improving almost immediately. During brexanolone administration, the patient must be carefully watched for severe sedation or loss of consciousness [18].

1.4.2 Non-pharmacological therapy:

1.4.2.1 Patient counselling:

- **Counseling aids:**

When information is given to a patient verbally, there is a risk that the patient will forget it over time. To aid with patient counseling, a range of teaching and educational aids have been developed. If the material is delivered in a printed format, the patient can review it at his or her leisure and whenever it is needed. Medication cards can be helpful, especially for patients who are on long-term drugs. A medication card is a written summary of a patient long-term medications that is provided in a way that the patient can understand. Cards can be handwritten or created by a computer. When a card is given to someone, it has also been proven that educating patients using a combination of oral and written information is more successful. It permits them to refer to it if they forget what they heard. Counseling could benefit from the use of films, graphics, and other resources. Posters, computer-generated booklets, pictograms, and a telephone system are among the various counseling tools that pharmacists can use. In the country, computer-assisted counseling is not yet well-known. Effective counseling and patient adherence can be expected when using modern strategies. The pharmacist should be present at the point of sale to assist the patient in choosing an OTC drug, suggesting non-pharmacological therapy, or referring the patient to a physician. Patients are also taught how to treat themselves in emergency situations, when to consult a doctor, and when diagnostic tests are required by pharmacists. As a result, the counseling process is likely to continue to improve patient understanding, patient compliance, and pharmacist job satisfaction. It also enhanced the relationship between pharmacists and their patients [19].

- **Cognitive behavior therapy:**

Cognitive behavior therapy (CBT), a well-studied and effective treatment for major depression is based on the idea that mood is influenced by both perceptions and behaviors. CBT focuses on assisting depressed mothers in changing showed negative thinking processes and implementing behavioral adjustments that improve copying and reduce discomfort**.**

- **Interpersonal therapy:**

Interpersonal therapy (IPT) is a short-term treatment for major depression that focuses on the link between interpersonal difficulties and mood, framing PPD as a medical illness that occurs in a social context. In IPT, the patient and clinician choose one of four interpersonal problem areas (role transition, role conflict, bereavement, or interpersonal deficits) to focus on during treatment. Throughout the therapy (which normally lasts 12 to 20 weeks), strategies are explored to aid individuals in altering dysfunctional relationship approaches and establishing stronger social supports. The fact that IPT is both time limited and problem - focused fits well with the needs of PPD. IPT has been customized to address problem areas important to PPD such as the interaction between mother and infants, mother and partner, and transition back to work.

- **Family and marital therapy:**

In the treatment of women with mood and anxiety disorders during pregnancy or the postpartum period, the role of the spouse and family is crucial. According to a recent study, women with PPD recover faster when their partners are supportive. Supportive psychotherapy includes providing comfort, reassurance, and knowledge to patients and their families in addition to other psychosocial therapies and/or medicines. Supportive psychotherapy may be the sole treatment a woman receives if her depression symptoms are too severe for her to engage in cognitive behavior or if she refuses pharmacotherapy. It is utilized to keep track of her mental state in such circumstances.

1.5 Medication adherence:

Medication adherence is described as the patient active, voluntary, and collaborative participation in a mutually acceptable course of behavior in order to achieve a therapeutic result [20, 21]. Adherence is defined as the degree to which a person behavior such as taking medication, following a diet, or making lifestyle changes matches to the provider agreed-upon recommendations Poor medication adherence leads to unnecessary disease progression and complications, reduced functional abilities and quality of life, more medical cost and physician visits, increased use of expensive, specialized medical resources, unneeded medication changes [22]

Measurement of medication adherence:

1.5.1. Subjective measurements: Questionnaire based approach in asking patient's about their medicine taking behavior. A number of questionnaires have been used by researchers in their regard including:

Morisky medication adherence scale (See fig: 2), Self-efficacy for appropriate medication use (SEAMS), Brief medication questionnaire (BMQ), The hill –bone compliance scale, Medication adherence rating scale (MARS), Adherence to refills and medications scale (ARMS), Scale for measurement adherence to medication applied in Zagreb, Croatia (Culig).

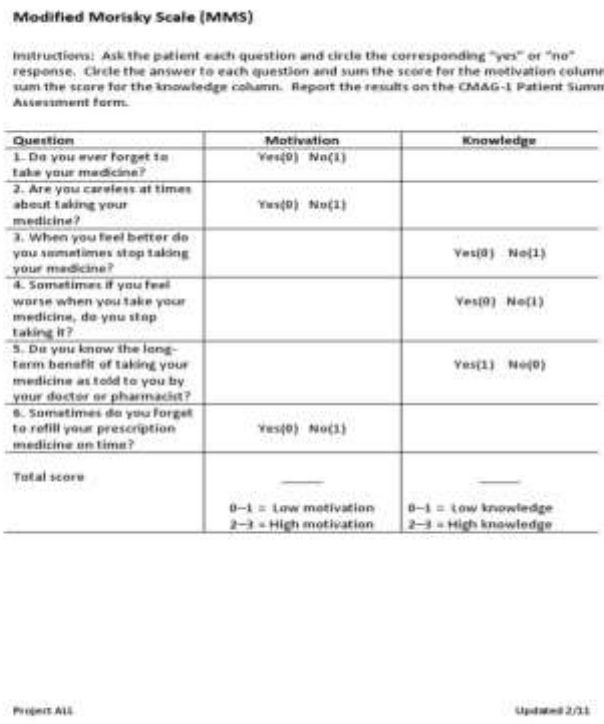
1.5.2. Objective measurements: The direct monitoring of patient medication adherence patterns using pill counts and electronically monitored medication adherence has shown promise and validation.

Counting pills/ examining pharmacy refill record and Electronic medication event monitoring systems (MEMS).

1.5.3. Biochemical measurements:

Adding a nontoxic marker to the medication, detecting its presence in blood or urine and measurement of serum drug levels

In disease condition patients, a healthy adherence effect has been seen, as indicated by enhanced treatment outcomes in patients who otherwise follow prescribed lifestyle and treatment activities. Patients who take their medications on a regular basis are more likely to follow lifestyle recommendations and have better illness outcomes [23, 24].



Modified Morisky Scale (MMS)

Instructions: Ask the patient each question and circle the corresponding "yes" or "no" response. Circle the answer to each question and sum the score for the motivation column and sum the score for the knowledge column. Report the results on the CMAG-1 Patient Summary Assessment form.

Question	Motivation	Knowledge
1. Do you ever forget to take your medicine?	Yes(0) No(1)	
2. Are you careless at times about taking your medicine?	Yes(0) No(1)	
3. When you feel better do you sometimes stop taking your medicine?		Yes(0) No(1)
4. Sometimes if you feel worse when you take your medicine, do you stop taking it?		Yes(0) No(1)
5. Do you know the long-term benefit of taking your medicine as told to you by your doctor or pharmacist?		Yes(1) No(0)
6. Sometimes do you forget to refill your prescription medicine on time?	Yes(0) No(1)	
Total score	____ 0–1 = Low motivation 2–3 = High motivation	____ 0–1 = Low knowledge 2–3 = High knowledge

Project ALL Updated 2/11

Figure 2: Edinburgh postnatal depression scale

II. RESEARCH METHODOLOGY:

2.1 Place of study: The study, "Impact of patient counseling and medication adherence in postpartum depression patients: a prospective observational study at tertiary care hospital, Ongole", which was carried out in the 'Department of Gynecology' IP at Government General Hospital (GGH), Ongole, a 750 bedded multi – disciplinary tertiary care teaching hospital.

2.2 Period of study: 6 months

2.3 Type of study: Prospective observational study

2.4 Study population: 148 cases

2.5 Patient enrollment: Patients are enrolled in the study based on inclusion and exclusion criteria

a. Inclusion criteria:

People who are willing to participate.
The postpartum women who are completed 7 days were included.
From 18 to 50 age group of post-natal women were included.

b. Exclusion criteria:

People who are not willing to participate.
Below 18 years of postnatal women were excluded.
Women with chronic diseases like HIV, TB, and Cancer were excluded.

2.6 Study materials:

Patient Data Collection Form

A specially designed questionnaire was adapted from "Edinburg Depression Scale and Rcog Women's Survey of Maternal mental Health and modified morisky scale for medication adherence"

It consists of two parts Part-A, Part- B and part –c.

The Part-A assess patient personnel data and social and past medical history
The Part-B assess the postpartum depression level.
The Part-C assess the medication adherence.

Patient Inform Consent Form

The details of the patient and complaints were done after the informed consent taken from the patient.

2.7 Method of study:

Subjects were included based on eligibility criteria .and assess the postpartum depression level and medication adherence by using questionnaire. A questionnaire was prepared for the assessment of postpartum depression level and medication adherence.

The data was collected from postnatal women's by using questionnaire form who are admitted in gynecology department in tertiary care hospital [GGH]. 15 -20 min is given to subjects to fill the questionnaire; if the subjects are illiterate then they can use the help of the others to fill the questionnaire. Based on the estimated level of depression, subject is counseled by counselor.

In this study we conduct two to four sessions for each patient with the time period of 1-2 months and also analyze the medication adherence. After getting the two to four sessions, data of each patient will be compared. The data collected from the subjects are analyzed for the impact of patient counseling and medication adherence using the statistical analysis.

2.8 Statistical analysis:

The association of clinical demographic characteristics was statistically analyzed by T test.

III. RESULTS AND DISCUSSION:

Age:

Figure 3 shows, prevalence of postpartum depression rate is 98.66%. Based on observed data, 18 to 24 years age group women were mostly affected and 31-40 years women were less affected.

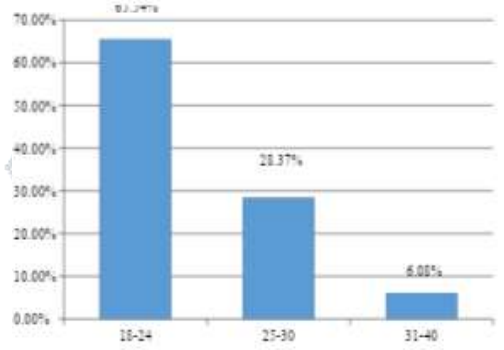


Figure 3: Age wise distribution

Marital status:

Figure 4 shows, married women were mostly affected when compared to unmarried and divorced.

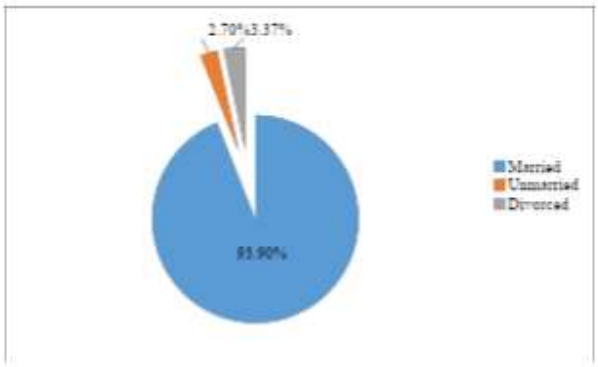


Figure 4: Marital status wise distribution

Risk Factors:

Figure 5 shows the risk factor of postpartum depression patients is highly affected by the abortions.

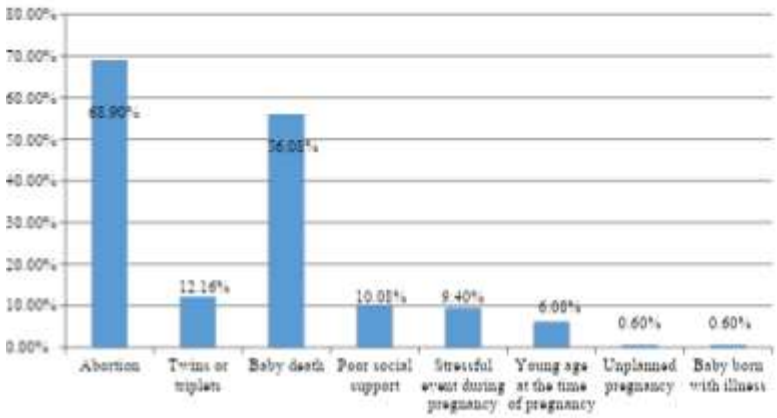


Figure 5: Risk factors wise distribution

Patient Counseling:

Table 1: Categorization based on follow up attendance

Follow ups	1st Follow up	2nd Follow up	3rd Follow up
Attended	148(98%)	143(95%)	142(94.6%)
Not attended	2(1.3%)	7(4.6%)	8(5.3%)

Table 1 shows, for first follow up 148 patients were attended. For second and third follow up 143 and 142 patients were attended.

Medication adherence:

Table 2: Categorization based on medication adherence

Adherence	Baseline	1st Follow up	2nd Follow up	3rd Follow up
Medication adherence	0	51(34.4%)	89(62%)	139(98%)
Medication non adherence	150	97(65.4%)	54(38%)	3(2.1%)

Table 2 shows patients after counselling, the adherence rate has increased from follow up to follow up i.e. 34.4% to 98%.

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