

# Perceptions and Efficacy of Brexanolone for the Treatment of Postpartum Depression: A Mixed Methods Analysis

Aaron Salwan, PharmD, MPH<sup>1</sup>, Megan Maroney PharmD BCPP<sup>1,2</sup>, Lisa Tremayne, RN, CPPD, CBC<sup>2</sup>.

Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, New Brunswick, NJ;<sup>1</sup> Monmouth Medical Center-RWJBarnabas Health, Long Branch, NJ<sup>2</sup>

## Background

- Brexanolone (BRX), an aqueous form of the steroid allopregnanolone, is thought to improve depressive symptoms after childbirth by modulating neuronal excitability through positive allosteric modulation of the GABA type-A receptor.
- BRX has demonstrated efficacy for the treatment of postpartum depression (PPD), particularly in persons with moderate to severe depression that begins in the third trimester or within 4 weeks after birth.
- Phase 3 clinical trials evaluated the efficacy of BRX up to day 30 (Meltzer-Brody et al., 2018).
- As 40% of women experience their first episode of depression during the postpartum period, (Wisner et al., 2013) and untreated PPD increases the risk of depression 6-fold later in life, (Josefsson & Sydsjö, 2007) investigating the utilization of BRX is warranted.
- The following highlights the journey of 10 women with treatment refractory PPD who received treatment with BRX at Monmouth Medical Center in Long Branch, NJ.

## Methods

- A retrospective chart review was performed to assess for a change in depressive symptoms based on Edinburgh Postnatal Depression Scale (EDPS) ratings documented in the electronic health record during the BRX infusion and up to 150 days post-infusion.
- Semi-structured interviews based on the Theory of Planned Behavior will be recorded and transcribed in order to conduct thematic analysis using NVIVO software.

## Purpose

- The purpose of the proposed research is to further understand the lived experience of women who have received brexanolone.
- Further, we will evaluate the real-world efficacy of brexanolone during the 60-hour infusion and beyond 30 days.

## Results

### Baseline Demographics and Characteristics

Age (Mean=36.1)	Race	BMI (Mean=27.14)	Medical History	Current Treatment for Depression / Anxiety	Obstetric History	Time Until BRX (weeks) (Mean= 21.3)
33	White	26.4	Hypothyroidism	Sertraline, clonazepam	G2P1	16
34	White	33.8	MDD	Bupropion, sertraline	G2P2	36
37	White	29.6	MDD	Propranolol, lorazepam	G3P3	24
36	White	39.2	MDD; gestational HTN	Venlafaxine XR, alprazolam	G1P1	24
36	White	23	IVF, GAD, AUD, Hypothyroidism	Venlafaxine, clonazepam	G3P3	15
31	White	22.3	Gestational HTN, preterm labor, gestational thrombocytopenia	Clonazepam	G3P1	20
34	White	20	Pre-eclampsia, scoliosis	Sertraline, clonazepam	G2P2	26
40	Asian	22.3	IVF, OCD, bulimia, MDD	Sertraline, lorazepam	G1P1	14
49	White	28.1	Infertility, HTN	Sertraline, clonazepam	G5P2	16
31	White	26.7	ADHD, anxiety	Sertraline, alprazolam	G3P3	22

### Qualitative Interview Questions Based on Constructs from the Theory of Planned Behavior

#### Attitudes

- What do you believe are the advantages to receiving brexanolone for the treatment of PPD?
- How important is brexanolone in treating your PPD?
- Do you think receiving brexanolone was a good idea? Why?
- Would you recommend brexanolone to other women with PPD?
- The brexanolone infusion improved my relationship with my child.
- The brexanolone infusion improved my relationship with my partner.

#### Social Norms

- What individuals or groups would approve of you receiving brexanolone for PPD?
- Most women with PPD should receive treatment for PPD.
- Most women experiencing PPD communicate with their doctor about their symptoms.
- Most people who are important to me think it was a good idea to receive treatment with brexanolone.
- My family was ashamed of me for receiving brexanolone.
- My partner thinks I should receive treatment for PPD with brexanolone.

#### Perceived Behavioral Control

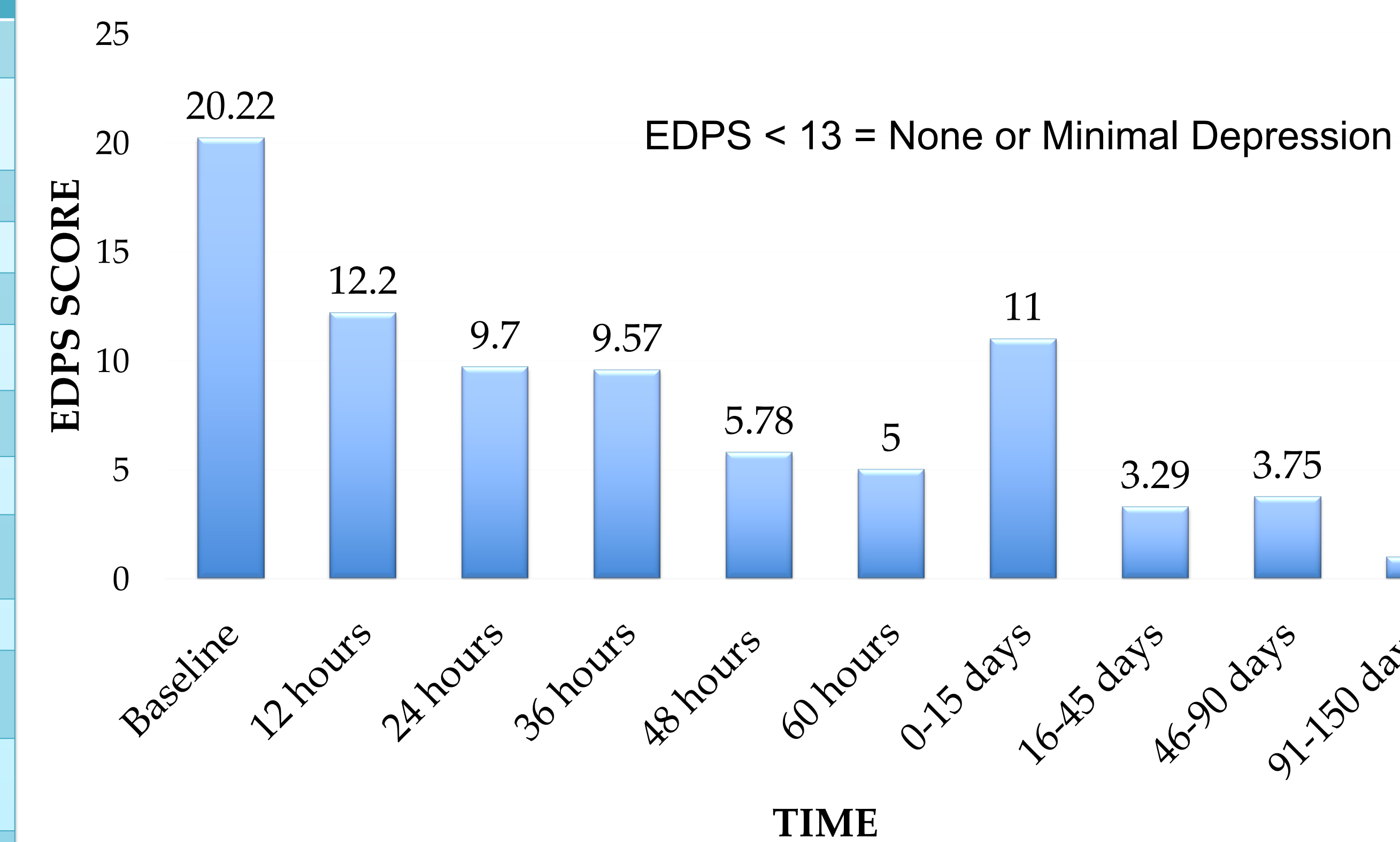
- What circumstances enabled you to receive brexanolone for the treatment of PPD?
- What circumstances would make it difficult for you to receive brexanolone?
- How confident were you that brexanolone would relieve your depressive symptoms?
- How confident were you in talking to your healthcare provider about options to help manage PPD?
- Describe your ability to cope with PPD.
- Whether or not I received brexanolone for PPD was entirely up to me.
- Receiving brexanolone is feasible in my community.
- I was confident in my ability to receive treatment with brexanolone, despite having a small child.
- Treatment for PPD with brexanolone is widely available.

## Results Continued

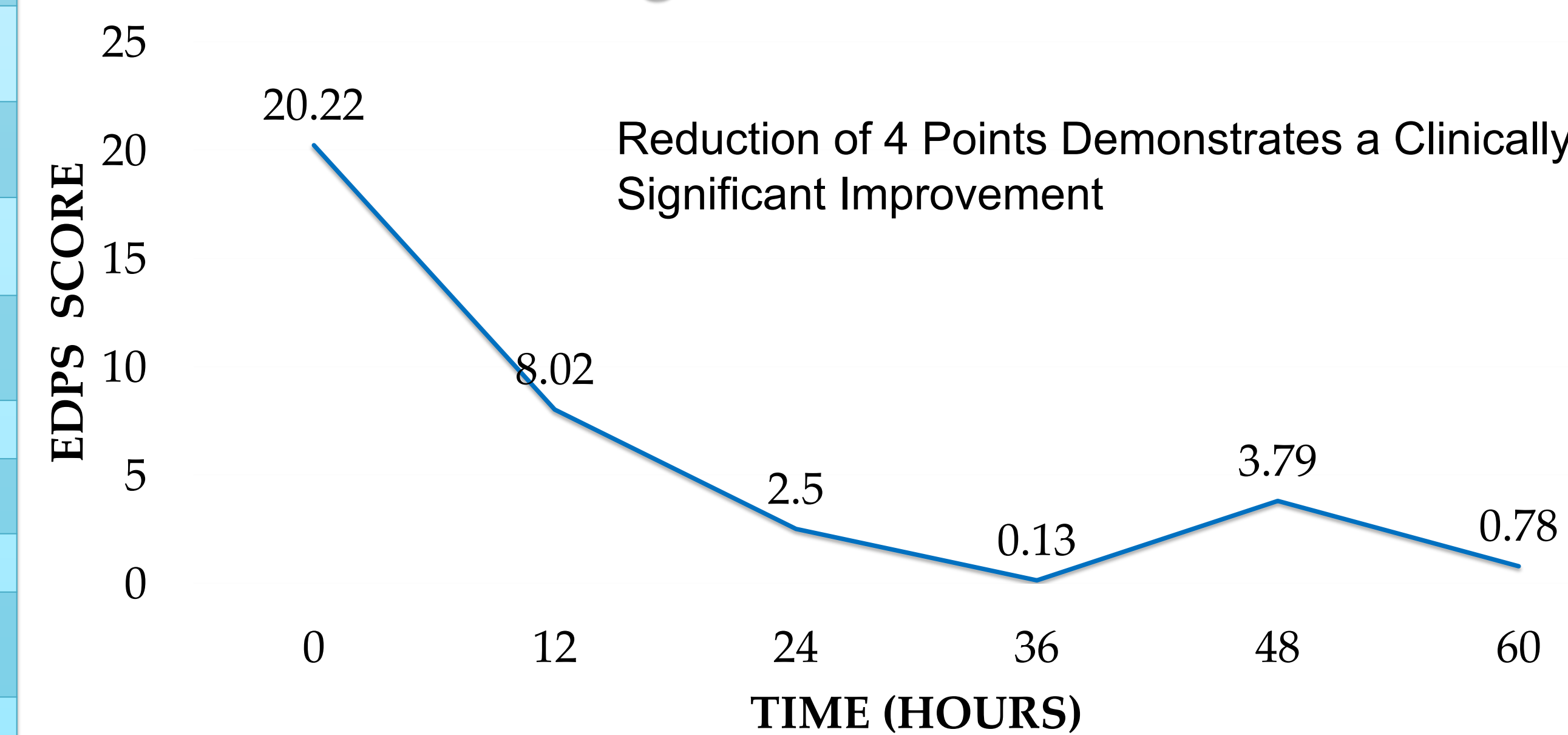
### Statistical Analysis

Time	Mean (SD)	95% Confidence Interval of the Difference	P-Value *P < 0.05
Baseline	20.22 (4.27)	-	-
12 Hours	12.2 (4.61)	3.58 to 11.31	0.002*
24 Hours	9.7 (5.98)	6.4 to 14.04	< 0.001*
36 Hours	9.57 (7.55)	5.53 to 17.32	0.003*
48 Hours	5.78 (6.16)	9.88 to 19.01	< 0.001*
60 Hours	5 (6.41)	9.34 to 20.91	< 0.001*
> 30 days	2.56 (3.75)	15.43 to 22.57	< 0.001*

### Mean EDPS Scores Over Time



### Difference in EDPS Scores During 60-hour Infusion



## Discussion

- Women experienced a statistically significant reduction in depressive symptoms within 12 hours.
- Reduction in depressive symptoms was maintained beyond 30 days post infusion.
- Brexanolone's rapid onset of action may play a role in preventing infanticide and maternal suicide while improving maternal bonding and child development.
- Semi-structured interviews are yet to be performed.
- Increased availability of brexanolone has the potential to change the status quo of treatment for PPD.
- Additional research is warranted to understand physician's intentions to prescribe brexanolone and to compare development outcomes of children of mother's treated with brexanolone.

Research reported in this publication was supported by the College of Psychiatric and Neurologic Pharmacists Foundation Defining the Future Research Grant. The content is solely the responsibility of the authors and does not necessarily represent the official views of the CPNPF. Dr. Maroney is a member of the Otsuka EXCEL Speaker's Bureau and a consultant for Novus Medical Education. The other authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject of the subject matter of this presentation.