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Co-occurring Psychiatric Symptoms are Associated with Increased Psychological, Social and Medical Impairment in Opioid Dependent Pregnant Women

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Abstract

The interaction of psychiatric symptoms with drug dependence during pregnancy is not well understood. This study examines the relationship of psychiatric symptoms to severity of drug use and drug related problems among participants in a clinical trial of pharmacologic treatment of opioid dependence during pregnancy (N=174). 64.6% reported additional psychiatric symptoms (48.6% mood symptoms, 40.0% anxiety symptoms, and 12.6% suicidal thinking). Women who endorsed co-occurring psychiatric symptoms showed more severe impairment on the Addiction Severity Index (ASI). Further investigation is warranted to understand the effect of psychiatric symptoms on long-term maternal and neonatal outcomes.

BACKGROUND

Use of opioid drugs during pregnancy is an important public heath concern that is known to affect over 100,000 women and infants annually in the United States. In 2007, the National Survey on Drug Use and Health (NSDUH) reported past year use of opioid analgesics without proper medical oversight in 5.2% of pregnant women aged 15 to 44.[1] This annual report also notes continued increases in non-medical use of prescription pain relievers over the past 5 years. Opioid dependence during pregnancy is associated with adverse birth outcomes due to complex medical, psychiatric and social circumstances.[2] Growing evidence suggests that opioid agonist treatment of opioid dependence during pregnancy promotes better heath for mother and infant alike.[2] Use of methadone during pregnancy has been

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Declaration of Interest
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extensively studied and found to be safe and effective in improving maternal health and birth outcomes.[3] Buprenorphine, a partial agonist at the μ-opioid receptor, is an alternative to methadone that has also been found to be safe and equally effective as methadone in non-pregnant patients.[4,5] Although neither medication is approved by the FDA for use during pregnancy, methadone maintenance is the established standard of care given over 40 years of clinical and research experience with it. Randomized controlled trial data comparing methadone and buprenorphine under double-blind conditions demonstrated that methadone and buprenorphine produced similar maternal outcomes and that buprenorphine was at least as safe as methadone for the neonate.[6,7] Data from a retrospective study suggests that buprenorphine may have advantages over methadone for treatment during pregnancy including longer gestation, greater birth weight and less frequent and less severe signs of neonatal abstinence syndrome.[8]

Analysis of NSUDH data from 2002-2003 studied women with children in the home and found that those with substance use disorders were more likely to be diagnosed with a serious mental illness (Odds Ratio 3.7).[9] Similarly, the landmark Epidemiologic Catchment Area Study found that 53% of individuals diagnosed with drug dependence also had another psychiatric diagnosis.[10] In follow-up on this work, however the National Comorbidity Study (NCS) found that only 20% of individuals with substance use disorders had symptoms of a mood disorder while 17% endorsed symptoms of an anxiety disorder. [11]

The prevalence of psychiatric disorders during pregnancy is not well established. In a systematic review, Bennett et al. estimated the prevalence of major depression during pregnancy to be between 7-16%, with greater risk occurring later in pregnancy.[12] Less is known about the prevalence of bipolar disorder during pregnancy. Bipolar disorder occurs much less frequently in the general population with a lifetime prevalence of about 1%, but has a high rate of comorbidity with substance use disorders.[10,11,13]

Fitzsimons et al. reported prevalence estimates of mood or anxiety disorders as high as 75% in opioid dependent pregnant women. In their sample, co-occurring psychiatric symptoms had a negative effect on treatment outcomes, with depressed women being more likely to test positive for drugs during treatment.[14] Further analysis of this cohort showed that babies born to women with mood disorders stay in the neonatal intensive care unit (NICU) longer than those without.[15]

Previous work from our group described the prevalence of psychiatric symptoms and reported the frequency of prescribed psychotropic medications in opioid dependent pregnant women.[16] The current study further examines the prevalence of co-occurring psychiatric symptoms in an expanded sample and explores the relationship between psychiatric symptoms and severity of drug use and drug related problems.

METHODS

Study Design

This study used cross-sectional data that were collected as a part of the Maternal Opioid Treatment: Human Experimental Research (MOTHER) study. The MOTHER study is a double-blind, randomized controlled trial performed at eight sites. The major goal of the MOTHER study is to evaluate the safety and efficacy of buprenorphine and methadone in pregnant opioid dependent women and their neonates. All sites received local Institutional Review Board approval. Oversight was conducted by a Data and Safety Monitoring Board.

Subjects

Opioid dependent pregnant women between the ages of 18 and 41 years, carrying a single fetus with an estimated gestational age of 6 to 30 weeks at study entry and a normal fetal heartbeat identified by sonogram were eligible for screening. All women included in the study met DSM-IV criteria for current opioid dependence and demonstrated current opioid use by providing a positive urine sample. Women currently receiving opioid agonist treatment were eligible to participate. Exclusion criteria included: (1) a medical condition making participation medically hazardous (e.g., HIV, preterm labor, evidence of congenital malformation, abnormal fetal heartbeat); (2) an acute severe psychiatric condition in need of immediate treatment or which represented an imminent risk of harm to the woman herself or others; (3) a current diagnosis of benzodiazepine or alcohol abuse or dependence; (4) regular use of alcohol or benzodiazepines in the past 30 days (because of pharmacologic contraindications); (5) a positive alcohol breath test or benzodiazepine positive urine drug screen during screening; (6) pending legal action that could interfere with participation. Alcohol and other drug use was monitored regularly during the study, and contingency management techniques were used to lessen the risk of concomitant drug use during pregnancy.

Subjects were recruited from obstetric clinics at participating hospitals, local methadone maintenance treatment programs, and through local advertising. Seven of the eight sites successfully recruited and randomized subjects for participation. In all, 1074 women were given an initial screening assessment. Of those, 519 were eligible and 438 were available to be approached for further screening. Among those approached, 208 (47%) consented to participate. A comprehensive screening assessment based on inclusion criteria revealed that 188 women who consented were fully eligible to participate in the study (38 women were excluded due to severity of psychiatric illness), and ultimately 175 were randomized into the study. One woman was excluded from analysis due to missing data on the ASI, yielding a final analytic sample size of 174.

Assessment of Substance Use Disorder

The E module of the SCID I[17] was administered during screening to assess current and lifetime substance use disorders. Training on the administration of the SCID-E included a didactic review of DSM-IV criteria for Axis I disorders, a standardized review of the SCID instrument, and observation of videos purchased from the test makers. In addition, two mock interviews were reviewed by an expert reviewer for concordance between expert trainer and interviewer. Finally, interviewers were required to pass a knowledge assessment pertaining to DSM-IV criteria for substance abuse and/or dependence. Ongoing review of the interviewers' administration was conducted periodically.

Screening for Presence of Co-occurring Psychiatric Disorders

The screening version of the Mini International Neuropsychiatric Interview[18] (MINI) was administered to all potentially eligible participants to assess symptoms of other co-occurring psychiatric disorders. The MINI was designed as a diagnostic instrument for reliable identification of Axis I psychiatric illness. The MINI has been used in several studies to evaluate the presence of psychiatric conditions in opioid dependent individuals.[19,20] The shorter screening tool is used to determine whether further clinical assessment for psychiatric illness is indicated. We used the screening version in the current study in order to reduce response burden on subjects. The items used in the MINI-screen are listed in our earlier work.[16]

Data Analysis

Descriptive statistics for the 174 participants were calculated using SPSS 16.0. MANOVAs were used to compare mean Addiction Severity Index (ASI) composite scores adjusted for race, employment status, marital status, legal issues and site of women who did and did not report symptoms related to each of 11 disorders: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Hypomania, Dysthymia, Panic Disorder, Agoraphobia, Social Phobia, Post Traumatic Stress Disorder (PTSD), Suicidality, Bulimia, and Obsessive Compulsive Disorder (OCD).

RESULTS

Sample Characteristics

Table 1 describes the demographic characteristics of the sample. The mean age of participants was 27.3 (SD 5.9). Subjects were enrolled with a mean estimated gestational age of 17.1 weeks (SD 6.3). Participants had completed, on average, 11.4 (SD 2.0) years of formal education. The majority of the women enrolled in the study were white (83.3%), never married (71.8%), and unemployed (86.8%). Legal issues were a factor for 17.8% of women with 2.3% on parole, 13.8% on probation, and 1.7% awaiting trial. The proportion of subjects enrolled at each site is listed.

Prevalence of psychiatric symptoms

A large majority of women in our sample (64.6%) endorsed symptoms that resulted in a positive screen for one or more psychiatric diagnosis. 48.6% endorsed symptoms of a mood disorder, 40.0% an anxiety disorder and 12.6% reported suicidal thinking at some point in the past 30 days. The median number of symptoms endorsed by women in our study was 2. Almost one-third (32%) of women reported symptoms consistent with a diagnosis of MDD, 31% endorsed symptoms of dysthymia, and 39% had symptoms consistent with a hypomanic episode. Anxiety symptoms fell into the following diagnostic categories: 40% of subjects reported symptoms consistent with GAD, 26% Panic Disorder, 22% Agoraphobia, 16% Social Phobia, and 16% PTSD, and 3% OCD. Less than 1% of our sample reported symptoms consistent with Bulimia.

Relationship between psychiatric symptoms and impairment as measured by the ASI composite scores

Table 2 presents a comparison of ASI composite scores by the presence or absence of reported psychiatric symptoms. Significant differences in severity of impairment in the domains measured by ASI emerged in the areas of Family/Social Functioning and Psychological Functioning across all putative diagnoses. Differences in Medical Impairment occurred for subjects endorsing features of MDD, hypomania, panic disorder, and social phobia. Significant differences were present for Employment Status for hypomania, panic disorder, agoraphobia, and OCD. In the area of severity of drug use, significant differences were found for subjects endorsing symptoms of MDD, GAD, hypomania, dysthymia, PTSD, and suicidality.

DISCUSSION

This study adds to a growing body of literature that describes the clinical features opioid dependent women during pregnancy. The data presented here concur with other reports that the presence of co-occurring psychiatric symptoms is common and has an impact on severity of opioid dependence during pregnancy. Previous work[14] has discussed mood and anxiety disorders generally. Our study extends our current understanding of the interaction between opioid dependence and co-occurring psychiatric symptoms during pregnancy.

A large majority (50.3%) of our sample presented with symptoms of a co-occurring psychiatric illness. Because we utilized a screening tool rather than full diagnostic assessment, it is not entirely clear based on our data whether these women would meet full diagnostic criteria for an Axis I disorder. However, based on data from the NCS suggesting high rates of comorbidity in substance use disorders, we suspect that many of these women would meet criteria for mood or anxiety disorders in addition to opioid dependence.[11] It is possible that some of these mood and anxiety symptoms were substance-induced. Data from the present study do not allow for clarification of this question. Data from the NCS suggests that in a large community sample only a very small proportion of mood and anxiety symptoms were a direct result of substance abuse. The rate of opioid dependent individuals in that sample was quite low, however, making it difficult to know whether those findings are generalizable to the current sample.[11]

The prevalence of depression observed (33%) was consistent with the findings of Fitzsimons et al. from their study of opioid dependent pregnant women in methadone maintenance treatment.[14] In their sample, co-occurring mood disorders were associated with increased impairment in only social and psychiatric components of the ASI. We found greater severity in these areas as well as medical and drug related problems. This finding suggests that the problems encountered by women with co-occurring depression are wide-reaching and further reinforces the recommendation for adequate screening for and treatment of co-occurring psychiatric symptoms during pregnancy.

PTSD was relatively rare (16%) in our sample compared with other studies of women with substance use disorders. For example, a study of a community sample in Australia reported that one third of opioid dependent individuals also had symptoms of PTSD.[21] This discrepancy may be related to lack of adequate screening for traumatic events in our sample, reflecting a limitation of the MINI screener. Use of specific screening tools for PTSD in this population may be indicated to ensure that these symptoms are adequately assessed and treated.

The percentage of women in our study who endorsed hypomania (39%) was quite high. Because our study used a screening question and did not follow-up with a formal diagnostic interview, it is difficult to be certain that a positive response represents true hypomania as defined in DSM-IV. However, others have observed higher prevalence estimates of mania and hypomania among individuals with substance use disorders as compared to the general population. Grant et al. reported that illicit drug dependence conferred the greatest risk of mania with an odds ratio of 13.9 (compared to non-drug dependent individuals).[22] Hypomania during pregnancy has not been well characterized. The diagnosis of mood symptoms during pregnancy may be affected by ideas about normal emotional fluctuations and hormonal changes during pregnancy. Formal evaluation of hypomania deserves greater attention in this population. The large proportion of women in our sample reporting mood and anxiety symptoms suggests that all pregnant women entering treatment for opioid dependence would benefit from assessment and treatment for co-occurring psychiatric illness. This study lends further support to the growing trend toward concurrent and integrated treatment for substance use disorders with other co-occurring psychiatric illness.[23,24] Screening for psychiatric symptoms during pregnancy can be confounded by symptoms of pregnancy itself (e.g., sleep disruption, fatigue, etc.). Treatment during pregnancy is complicated by the need to balance the effects of treatment on the patient as well as her unborn child. While the evidence regarding risks for the fetus of exposure to psychotropic medications is mixed, several studies suggest that women with depression and bipolar disorder who discontinue medications during pregnancy are at greater risk of recurrence of mood symptoms.[25-28] Further systematic study of both medication management and non-pharmacologic treatment is needed to determine best practice for

treatment of opioid dependence and co-occurring psychiatric illness during pregnancy. Any treatments employed must ultimately balance needs of the mother and her unborn child.

The presence of co-occurring psychiatric symptoms in our sample was associated with increased impairment across multiple domains of functioning as measured by the ASI. After breaking the blind in our randomized controlled clinical trial, it will be possible to evaluate the extent to which psychiatric symptoms are associated with maternal and neonatal outcomes.

There are several limitations of the present work. First, our study utilized a screening tool, but did not allow for systematic formal diagnosis of psychiatric illness. Therefore, we cannot state with certainty the prevalence of co-occurring Axis I disorders in this sample. Furthermore, this study used a cross-sectional design, and thus we cannot make claims about the directionality of the association between psychiatric symptoms and functional impairments. Longitudinal studies would be required to understand the evolution of these symptoms throughout the course of pregnancy. Our study did not include any evaluation of Axis II psychiatric disorders, known to commonly co-occur with substance use disorders.[29,30] Axis II disorders may have important implications in longer term outcomes for the mother-infant dyad because of their potential to affect attachment[31,32] as well as longer term adherence to addiction and psychiatric treatment.[33]

Finally, the current study provides limited information about concomitant use of other drugs of abuse. Future research should examine the impact of concomitant drug use patterns during pregnancy on psychiatric symptoms.

Given that symptoms of psychiatric illness are quite prevalent during pregnancy in opioid dependent women and that these symptoms are indicative of poorer functioning in several domains, these findings highlight the importance of evaluating and treating co-occurring psychiatric illness in opioid dependent women during pregnancy. Moreover, further investigation is warranted to understand the effect of psychiatric symptoms on long-term maternal and neonatal outcomes.

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Table 1

Sample Characteristics (*N* = 174)

Demographics	**Mean (SD)**
Age (years)	27.3 (5.9)
Estimated Gestational Age (weeks)	17.1 (6.3)
Education completed (years)	11.4 (2.0)
Race/Ethnicity:	**n (%)**
White	145 (83.3)
Black	24 (13.8)
Other	5 (2.9)
Marital status:	
Never married	125 (71.8)
Married	22 (12.6)
Widowed	3 (1.7)
Divorced	12 (6.9)
Separated	12 (6.9)
Employed	23(13.2)
Legal status:	
No Legal Issues	140 (80.5)
Parole	4 (2.3)
Probation	24 (13.8)
Impending trial	3 (1.7)
Unknown/Other	3 (1.7)
Site	
Baltimore	33 (19.0)
Burlington	30 (17.2)
Detroit	19 (10.9)
Philadelphia	30 (17.2)
Providence	4 (2.3)
Nashville	17 (9.8)
Vienna	41 (23.6)

Table 2

Addiction Severity Index Composite Scores by Putative MINI Diagnoses, Means adjusted for race, employment status, marital status, legal issues, and site

Psychiatric Symptoms	Addiction Severity Index (ASI) Composite Scores							
	Medical		Employment		Alcohol		Drugs	
	X	p	X	p	X	p	X	p
MDD								
Yes (n = 56)	**0.35**	**.007**	0.83	.973	0.01	.464	**0.33**	**<.001**
No (n = 118)	**0.22**		0.79		0.01		**0.28**	
GAD								
Yes (n = 69)	0.29	.125	0.79	.192	0.01	.923	**0.31**	**.003**
No (n = 105)	0.24		0.81		0.01		**0.29**	
Hypomania								
Yes (n = 67)	**0.31**	**.023**	**0.79**	**.013**	0.00	.250	**0.31**	**.011**
No (n = 107)	**0.22**		**0.81**		0.01		**0.29**	
Dysthymia								
Yes (n = 55)	0.31	.155	0.83	.130	0.01	.020	**0.33**	**<.001**
No (n = 119)	0.23		0.79		0.01		**0.29**	
Panic Disorder								
Yes (n = 46)	**0.33**	**.031**	0.76	**.002**	0.01	.593	0.30	.210
No (n = 128)	**0.23**		0.82		0.01		0.30	
Agoraphobia								
Yes (n = 38)	0.31	.060	**0.74**	**<.001**	0.01	.798	0.32	.098
No (n = 136)	0.25		**0.82**		0.01		0.29	
Social Phobia								
Yes (n = 28)	**0.44**	**<.001**	0.82	.406	0.01	.269	0.31	.121
No (n = 146)	**0.22**		0.80		0.01		0.30	
PTSD								
Yes (n=28)	0.33	.072	0.81	.421	0.01	**.821**	**0.34**	**.005**
No (n=146)	0.25		0.80		0.01		0.29	

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Psychiatric Symptoms	Addiction Severity Index (ASI) Composite Scores									
	Medical		Employment		Alcohol		Drugs			
	X	p	X	p	X	p	X	p		
Suicidality										
Yes (n = 22)	0.35	.147	0.74	.430	0.01	.792	**0.33**	**.001**		
No (n = 152)	0.25		0.81		0.01		**0.29**			
Bulimia										
Yes (n = 13)	0.34	.271	0.84	.373	0.02	.093	0.32	.075		
No (n = 161)	0.25		0.80		0.01		0.30			
OCD										
Yes (n = 5)	0.17	.985	**0.66**	**.017**	0.00	.483	**0.37**	**.162**		
No (n = 169)	0.26		**0.81**		0.01		**0.30**			

	Legal		Family/Social		Psychological			
	X	p	X	p	X	p		
MDD								
Yes (n = 56)	0.12	.702	**0.38**	**.001**	**0.36**	**<.001**		
No (n = 118)	0.13		**0.27**		**0.14**			
GAD								
Yes (n = 69)	0.13	.325	**0.39**	**<.001**	**0.33**	**<.001**		
No (n = 105)	0.12		**0.25**		**0.13**			
Hypomania								
Yes (n = 67)	0.14	.245	**0.37**	**.003**	**0.32**	**<.001**		
No (n = 107)	0.12		**0.26**		**0.14**			
Dysthymia								
Yes (n = 55)	0.13	.298	**0.41**	**<.001**	**0.36**	**<.001**		
No (n = 119)	0.12		**0.26**		**0.14**			
Panic Disorder								
Yes (n = 46)	0.13	.441	**0.44**	**<.001**	**0.35**	**<.001**		
No (n = 128)	0.12		**0.25**		**0.16**			
Agoraphobia								

	Legal		Family/Social		Psychological	
	X	**p**	**X**	**p**	**X**	**p**
Yes (n = 38)	0.11	.465	**0.44**	**<.001**	**0.37**	**<.001**
No (n =136)	0.13		**0.27**		**0.16**	
Social Phobia						
Yes (n = 28)	0.11	.452	**0.40**	**.009**	**0.37**	**<.001**
No (n = 146)	0.13		**0.29**		**0.18**	
PTSD						
Yes (n=28)	0.13	.618	**0.44**	**<.001**	**0.36**	**<.001**
No (n=146)	0.13		**0.28**		**0.18**	
Suicidality						
Yes (n = 22)	0.06	.251	**0.39**	**.020**	**0.46**	**<.001**
No (n = 152)	0.14		**0.29**		**0.17**	
Bulimia						
Yes (n = 13)	0.17	.203	**0.51**	**<.001**	**0.38**	**<.001**
No (n = 161)	0.12		**0.29**		**0.20**	
OCD						
Yes (n = 5)	0.11	.569	**0.49**	**.051**	**0.48**	**<.001**
No (n = 169)	0.13		**0.30**		**0.20**	