A Comparison of Pregnancy-Only versus Mixed-Gender Group Therapy among Pregnant Women with Opioid Use Disorder

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Prenatal substance abuse is a significant problem associated with deleterious effects for both mother and child. Stigmatization of substance abuse in pregnancy may result in pregnant women's reluctance to seek treatment. This study aimed to determine whether treating pregnant women in pregnancy-only therapy groups improved outcomes compared with treatment in mixed-gender therapy groups. A randomized, controlled trial was conducted. Forty-five pregnant patients with opioid use disorders were randomized to either treatment as usual in mixed-gender groups or treatment in pregnancy-only groups. All patients received medication-assisted treatment with mono-buprenorphine sublingual tablets. Descriptive statistics, chi-square, Fisher's exact, and *t* tests were used for data analysis. Results showed no significant differences between the two groups with regard to relapse rates or retention in treatment. Satisfaction survey indicated that patients were equally satisfied with the two group experiences, but those in the pregnancy-only group rated group topic relevance significantly better than those in the mixed-gender group. The overall incidence of neonatal abstinence syndrome was 23%. These findings indicate no significant difference in outcomes between pregnancy-only treatment groups and mixed-gender treatment groups. Paramount in the treatment of pregnant patients with opioid use disorders is to reduce barriers to treatment and treat the opioid dependence itself.

KEY WORDS: *buprenorphine; group therapy; opioid use disorder; pregnancy; substance abuse*

Substance abuse among pregnant women is a significant public health problem affecting maternal and fetal health. Between 3% and 15% of pregnant women report substance abuse; however, studies of umbilical cord blood find the proportion of women abusing substances to be higher (Substance Abuse and Mental Health Services Administration, 2011). Anonymous sampling of cord blood in West Virginia found almost one in five infants exposed in utero to drugs or alcohol. The substances most commonly found, beside tobacco, were benzodiazepines, opioids, and alcohol, respectively (Stitely, Calhoun, Maxwell, Nerhood, & Chaffin, 2010). In studies among patients determined to be at high risk for substance abuse, 32% of infant cord tissue tested positive for drugs (Montgomery et al., 2008).

It is well documented that neonatal exposure to drugs and alcohol negatively affects fetal development and correlates with poor neonatal outcomes such as low birthweight, craniofacial abnormalities, microcephaly, neurological deficits, neonatal abstinence syndrome (NAS), and sudden infant death syndrome, all of which are associated with increased neonatal mortality (Minozzi, Amato, Vecchi, & Davoli, 2008; Pinto et al., 2010; Stitely et al., 2010). In addition, the care of infants affected by their mother's substance abuse is costly. Average hospital charges accrued by neonates with NAS are $53,400 per child, 77% of whom are Medicaid patients (Patrick et al., 2012). Medical complications for the mother are also common and include increased incidence of placental problems, premature delivery, and postpartum hemorrhage (Helmbrecht, Lewis, & Ebert, 2008).

Because of the stigma of having a substance use disorder (SUD) during pregnancy, the increasing culture of criminalizing substance use during pregnancy, and the fear of Child Protective Services intervention, pregnant women are often reluctant to seek treatment and often delay both prenatal care and substance abuse treatment (Hser & Niv, 2006).

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Delaying prenatal care puts both mother and fetus at risk of poor birth outcomes, and delaying substance abuse treatment increases the duration and intensity of neonatal and maternal exposure to harmful substances. Linking substance abuse treatment to prenatal visits has been associated with improved perinatal outcomes (Goler, Armstrong, Taillac, & Osejo, 2008).

Given these increased risks, decreasing barriers and increasing retention of pregnant women in treatment is essential. Determining the most effective ways of doing so for pregnant women also remains unknown, so we must turn to the body of research on gender-specific treatment. There are known distinct clinical differences between women and men presenting for substance abuse treatment. Women have earlier onset of use, more rapid progression to dependence, are more likely to have experienced child abuse and intimate partner violence, and have a higher incidence of co-occurring psychiatric disorders (Brady & Randall, 1999; Koos, Brand, Rojas, & Li, 2014; McHugh et al., 2013; Shand, Degenhardt, Slade, & Nelson, 2011; Unger, Jung, Winklbaur, & Fischer, 2010). Previous studies suggest that there are benefits to treating women with SUDs in female-only therapy groups, such as increased perceptions of safety and comfort among patients (Kauffman, Dore, & Nelson-Zlupko, 1995). Some studies of women treated in female-only substance abuse treatment groups have found better retention rates, greater treatment satisfaction among patients, and greater reductions in alcohol and drug use during posttreatment follow-up (Evans, Li, Pierce, & Hser, 2013; Greenfield, Cummings, Kuper, Wigderson, & Koro-Ljungberg, 2013). Other studies have shown mixed results in treating women in female-only versus mixed-gender groups (Greenfield et al., 2007). These findings, coupled with even greater clinical differences in presentation among pregnant women and the stigma associated with being pregnant and having an SUD, suggest in theory that pregnant women may have better retention and outcomes if treated in a pregnancy-only group where they may feel a greater sense of safety, interpersonal connection and freedom to share without being judged, and the ability to discuss gender- and pregnancy-specific issues.

Few studies have examined the different outcomes of pregnant women treated in pregnancy-only groups as compared with mixed-gender groups. Given that pregnant women have different clinical presentations than men, higher levels of shame and stigma, and more specialized medical and psychosocial concerns, it was thought that treating pregnant women in pregnancy-only groups would create a culture of greater safety and support, unlike what women would experience in a mixed-gender group. In a pregnancy-only group discussion could be facilitated around pregnancy- and delivery-related issues that would likely not occur in a mixed-gender group. Pregnant women in substance abuse treatment identify specific treatment needs, including a preference for group therapy, a need for strong social and sober networks, and pregnancy-related content in their groups (Kuo et al., 2013). A multidisciplinary treatment approach has been found to be most effective for this population (Metz, Köchl, & Fischer, 2012).

Medication-assisted treatment with buprenorphine has become an accepted standard of care treatment for opioid-dependent pregnant women (Jones et al., 2010; Kahila, Saisto, Kivitie-Kallio, Haukkamaa, & Halmesmaki, 2007; Lejeune, Simmat-Durand, Gourarier, & Aubisson, 2006; Mattick, Kimber, Breen, & Davoli, 2008). Multiple studies have indicated buprenorphine is at least as safe and efficacious as methadone with regard to multiple maternal and neonatal outcomes (Jones, Finnegan, & Kaltenbach, 2012; Kakko et al., 2007; Lacroix et al., 2004; Lejeune et al., 2006). Additional studies indicate reduced severity of NAS and shorter length of hospital stays among buprenorphine-exposed neonates versus methadone-exposed neonates (Jones et al., 2010; Winklbaur et al., 2008).

In this study, we sought to compare the treatment outcomes of pregnant women with opioid use disorders receiving treatment in pregnancy-only medication management and therapy groups with pregnant women receiving treatment in mixed-gender treatment-as-usual (TAU) medication management and therapy groups. All patients received medication-assisted treatment with buprenorphine. The content of both groups included cognitive–behavioral therapy (CBT) interventions, psychoeducation on the disease model of addiction, relapse prevention, and 12-step facilitation components. Given that the research suggests pregnant women want group content to include gender- and pregnancy-specific content (Kuo et al., 2013), and a multidisciplinary treatment approach has been found to be most effective for pregnant women in treatment for substance abuse (Metz et al., 2012), the pregnancy-only groups had additional content

including pregnancy-related topics such as labor and delivery, pain control at delivery, NAS, breastfeeding, and birth control. This content was provided by obstetrics and gynecology (OBGYN) and neonatal nurses, midwives, and lactation specialists. We hypothesized that women treated in pregnancy-only medication management and therapy groups would have increased retention, better treatment outcomes, and higher group satisfaction than pregnant women in mixed-gender TAU.

METHOD

Overview

Pregnant women with opioid use disorders entering medication-assisted treatment with buprenorphine were randomly assigned to either treatment in a pregnancy-only or TAU mixed-gender medication management and therapy groups. Participants were followed prospectively until four weeks postpartum. The study was approved by the institutional review board of West Virginia University.

Study Population

Women who presented between six and 30 weeks gestation to the Comprehensive Opioid Addiction Therapy (COAT) outpatient clinic were eligible to enroll in the study. Inclusion criteria included pregnancy with opioid use disorders and seeking medication-assisted treatment with buprenorphine. To meet eligibility, participants were required to obtain prenatal care and sign a release of information for study staff to abstract pregnancy and birth-related data from their medical record. Participants also were required to sign the COAT clinic treatment agreement guidelines. Exclusion criteria included diagnosis of active alcohol use, sedative-hypnotic use disorder, or untreated psychotic disorder; allergy to buprenorphine; having methadone in their system at time of intake; residence outside 90 mile radius of clinic or pending legal action that might result in incarceration during the term of their pregnancy.

Intervention

TAU consisted of medication management in a mixed-gender group setting using buprenorphine and group therapy in a mixed-gender group. The TAU group therapy conducted incorporated CBT, psychoeducation on the disease model of addiction, relapse prevention, and 12-step facilitation components. The intervention group consisted of medication management in a pregnancy-only group setting using buprenorphine and group therapy in a pregnancy-only group. The pregnancy-only group therapy conducted also incorporated CBT, psychoeducation on the disease model of addiction, relapse prevention, and 12-step facilitation components. In addition, once every six to eight weeks OBGYN-affiliated providers co-led a group discussion on pregnancy- and birth-related topics such as labor and delivery, pain control at delivery, NAS, breastfeeding, and birth control. As part of both the pregnancy group intervention and TAU, all participants were required to attend a minimum of four Narcotics Anonymous or Alcoholics Anonymous meetings weekly. Both medication management groups were conducted by board-certified psychiatrists and were 30 minutes in duration. Both therapy groups were run by licensed clinical therapists and were 60 minutes in duration.

Data Collection

During the intake visit but prior to randomization, participants underwent a drug and alcohol intake assessment completed by a licensed clinical therapist and, if eligible, were then asked for consent and interviewed by study staff, providing sociodemographic data and rating their quality of life (measured with the Quality of Life Inventory [QOLI] [Frisch, 1994]). Treatment data including days clean, reported relapse, urine drug screen (UDS) results, buprenorphine dose, and self-help meeting attendance were collected weekly during the clinic visits; every four weeks, participants were asked to complete a satisfaction survey rating their satisfaction with their group therapy. Information regarding delivery was abstracted from medical records. Participants also completed the Quality of Life Index at four weeks postpartum.

Study Variables

Outcomes were measured for our two primary dependent variables and included retention in treatment and relapse. Participants were not retained in treatment for four primary reasons: dishonesty about substance use, nonattendance at 12-step meetings, needing a higher level of care, and multiple no-shows. Relapse was assessed by results of UDS administered in treatment setting, as well as participant self-report of relapse. UDS results at time of delivery were extracted from the medical record. All participants signed a release of information for us to obtain these data and also the results of their infants' NAS diagnosis and treatment.

The following covariates were self-reported. Self-reported sociodemographic data included age group (≤ 18, 19–34, and ≥ 35 years), gestational age at intake (first, second, or third trimesters), marital status (single, married, divorced), educational attainment (some high school or less, high school diploma/GED, more than high school), and employment (full-time, part-time, or unemployed). Health insurance status was also assessed. However, due to the small number of women with private insurance ($n = 3$), this analysis is restricted to women receiving Medicaid ($n = 45$) to reduce the likelihood of confounding by health insurance type. Participants reported no other health insurance status.

Other self-reported covariates included information related to drug use (age of first drug use, days of use in the 30 days prior to intake), and legal problems (none; drug related; criminal, unrelated to drugs; or driving under the influence). Substance abuse and mental health comorbidities were assessed by a licensed independent clinical social worker at intake assessment using DSM-IV diagnostic criteria, the Beck Depression Inventory (Beck, Steer, & Brown, 1996), and the Beck Anxiety Inventory (Beck & Steer, 1993) assessment tools (screening for opioid, sedative, cocaine, or cannabis abuse or dependence and anxiety disorder, panic disorder, bipolar disorder, major depressive disorder, posttraumatic stress disorder, and others).

A secondary dependent variable was participant satisfaction with therapy group. Every four weeks participants were asked to complete a self-administered satisfaction survey related to their satisfaction with group therapy. All of the satisfaction responses were scored with a Likert scale (1 = not at all, 2 = slightly, 3 = somewhat, 4 = considerably, and 5 = greatly). Questions related to the therapist included comprehension of the leader and feeling accepted by the leader. Questions related to the group members included whether group members were supportive and feeling accepted by the other group members. Group members were also asked to what extent they felt comfortable participating and to what extent topics were relevant to them. Finally, group members rated the therapist–participant relationship.

Statistical Analysis

Frequencies were tabulated to describe the TAU and pregnancy-only groups. Chi-square tests were conducted to test for differences in categorical characteristics between the two groups. When expected cell counts were ≤ 5, Fisher's exact test was used. For continuous variables, *t* tests were used to examine the differences between the intervention and TAU groups; for ordinal variables such as change in quality of life and group satisfaction, a Cochran–Mantel–Haenszel correlation statistic with modified ridit scores was used to assess for differences between the groups. Satisfaction data were compared between the groups at four, eight, and 12 weeks post-enrollment. All analyses were performed in SAS version 9.3.

RESULTS

A total of 70 women were screened, and 50 of those women were eligible to participate in the study. Two women who were eligible declined to participate in the study because they requested to be in the pregnancy-only group. All three of the women with private insurance were assigned to the pregnancy-only group and were excluded. Of the remaining 45 women, 27 were randomly assigned to the pregnancy-only group and 18 to the TAU group. Hence, 45 participants are included in this data analysis (demographic details are presented in Table 1).

The majority (93%) of participants were 19 to 34 years of age. A third of the participants entered treatment during the first trimester, with another 44% entering during the second trimester. Fewer than a quarter sought treatment in the last trimester of pregnancy. Over three-quarters of participants were single, and only a third had received education past high school. No significant differences with regard to these characteristics existed between the treatment groups.

During treatment, fewer than a quarter (17% in both groups) of the women reported intimate partner violence during group therapy (data not shown). Twenty percent of the women reported legal problems. On average, participants started using drugs around age 14 years, with average initiation of opioids occurring in their late teens. The participants reported using drugs the majority of the 30 days before seeking treatment (about 26 and 24 days in the pregnancy-only and TAU groups, respectively). Few women reported or were diagnosed with current abuse of or dependence on substances other than opioids, and about half reported a co-occurring mental health disorder. Most common co-occurring substance use diagnosis was cannabis abuse or dependence. Two-thirds of women in the pregnancy-only group and half of the women in the TAU group tested positive for buprenorphine at their initial drug screen at intake. Average dose of buprenorphine

Table 1: Characteristics of Study Participants, by Treatment Group

Characteristic	Pregnancy-Only (*n* = 27)		Treatment as Usual (*n* = 18)		*p* Value[a]
	n (%)	*M* (*SD*)	*n* (%)	*M* (*SD*)	
Age group					
≤ 18 years	1 (4)		0		1.00
19–34 years	25 (93)		17 (94)		
≥ 35 years	1 (4)		1 (6)		
Gestational age at intake					
Trimester 1 (< 12 weeks)	11 (41)		4 (22)		.38
Trimester 2 (12–24 weeks)	10 (37)		10 (56)		
Trimester 3 (≥ 25 weeks)	6 (22)		4 (22)		
Marital status					
Single	22 (81)		15 (83)		1.00
Married	4 (15)		3 (17)		
Divorced	1 (4)		0		
Educational attainment					
Some high school or less	8 (30)		3 (17)		.33
High school diploma or GED	9 (33)		10 (56)		
More than high school	10 (37)		5 (28)		
Employment					
Full-time	2 (7)		2 (11)		.77
Part-time	3 (11)		1 (6)		
Unemployed	22 (82)		15 (83)		
Self-reported legal problems	23 (85)				
None	3 (11)		13 (72)		.42
Drug related	1 (4)		4 (22)		
Criminal, unrelated to drugs	0		0		
Driving under influence			1 (6)		
Self-reported age of first drug use					
Any drug		14.1 (2.0)		13.8 (1.8)	.62
Any opioid		19.1 (4.8)		18.1 (3.1)	.40
Self-reported drug use 30 days before intake		25.6 (7.8)		23.9 (8.9)	.49
Substance abuse diagnosis					
Opioid dependence	27 (100)		18 (100)		—
Sedative abuse or dependence	2 (7)		0		.51
Cocaine abuse or dependence	1 (4)		1 (6)		1.00
Cannabis abuse or dependence	3 (11)		3 (17)		.67
Mental health diagnosis[b]					
Any	14 (52)		9 (50)		0.90
None	13 (48)		9 (50)		

[a]Calculated using chi-square tests (categorical variables), Fisher's exact test (categorical data with expected cell counts < 5), and *t* tests (continuous data).
[b]Includes anxiety disorder, panic disorder, bipolar disorder, major depressive disorder, posttraumatic stress disorder, and others.

among the 45 women was 12 mg. No significant differences in these characteristics existed between the two treatment groups.

With regard to our two primary study variables, retention in treatment and relapse, of the 45 women, 52% of those in the pregnancy group and 50% in the TAU group *completed the study* ($p = .90$), which was defined as remaining in treatment until four weeks postpartum (study outcome data are presented in Table 2). The difference in these retention rates between the two groups was not significant. Reasons for noncompletion included dishonesty about substance use, noncompliance with 12-step meeting attendance, needing a higher level of care, and multiple no-shows. Nearly a quarter of women in both groups were referred to a higher level of care due to multiple relapses often in combination with mood liability and extreme psychosocial stressors. The retention rate was 52% in the pregnancy-only group and 50% in the TAU group.

Relapse was assessed by results of UDS during the course of treatment and at the time of delivery

Table 2: Study Outcomes, by Treatment Group

Outcome	Pregnancy-Only (*n* = 27)		Treatment as Usual (*n* = 18)		*p* Value[a]
	n (%)	*M* (*SD*)	*n* (%)	*M* (*SD*)	
Completion of study	14 (52)		9 (50)		.90
Reason for noncompletion					
Dishonesty about substance use	1 (8)		1 (11)		.68
Not going to 12-step meetings	1 (8)		0		
Required a higher level of care	3 (23)		2 (22)		
Multiple no-shows	5 (38)		5 (56)		
Other[b]	3 (23)		1 (11)		
Relapses					
Participants with at least one relapse		10 (37)		9 (50)	.39
Average relapses per participant		0.77 (1.3)		1.2 (1.8)	.41
Change in quality of life for those who completed study					.43
Quality of Life Inventory (QOLI) rating improved	1 (7)		3 (33)		
QOLI rating did not change	6 (43)		2 (22)		
QOLI rating declined	7 (50)		4 (44)		
Presence of neonatal abstinence syndrome (*n* = 22)					
Yes	3 (23)		2 (22)		1.00
No	10 (77)		7 (78)		

[a]Calculated using chi-square or exact tests (categorical data with and without expected cell counts < 5, respectively), Cochran-Mantel–Haenszel chi-square test (ordinal data), and *t* tests (continuous data).
[b]Other reasons for discharge included transfer to another clinic, incarceration, and elective abortion.

as well as participant self-report of relapse. Relapse rates were 37% in the pregnancy-only group versus 50% in the TAU group. Women in the pregnancy-only group were about 25% less likely to relapse than women in the TAU group, though the difference was not significant.

Of those who completed the study, 50% of women in the pregnancy-only group reported a decrease in their quality of life four weeks postpartum, 7% reported an increase, and 43% reported no change in their quality of life. This was in comparison to 44% of the women in the TAU group reporting a decrease in quality of life four weeks after delivery, 33% an increase, and 22% no change. An increase or decrease was considered a meaningful change if the individual's score changed classifications. Classifications included very low, low, average, and high. None of these differences between the two groups were statistically significant.

Of the 22 women for whom we successfully obtained delivery data, five (23%) had newborns with NAS severe enough to require medication intervention. The difference in the incidence of NAS between the two groups was not statistically significant. The presence of NAS and need for medication intervention was obtained from the pediatric medical record with the participant's consent.

With regard to our secondary dependent variable, the group satisfaction survey, the majority of women assigned to both groups were able to comprehend their therapy group leader. Most women in both groups also felt accepted by the therapist. Furthermore, the majority in both groups felt accepted by the other group members, and most also reported being comfortable participating. Most rated the therapist–participant relationship positively. There were no significant differences in any of these overall satisfaction ratings between the groups. However, the groups did differ significantly at four and eight weeks of treatment with regard to the relevance of topics ($p = .001$ and .016, respectively). The pregnancy-only group was more likely to rate the topics as greatly relevant (78% at four weeks and 81% at eight weeks) compared with the TAU group (29% at four weeks and 37% at eight weeks).

DISCUSSION

The primary aim of this study was to determine if there are any differences between treating pregnant women with opioid use disorders in pregnancy-only versus mixed-gender groups. The pregnancy-only group was intentionally designed to have very similar content as the TAU group to best assess whether the grouping of pregnant women with substance abuse problems together lent itself to a changed environment and therefore a different therapeutic experience. The women were almost exclusively of

lower socioeconomic status (SES), primarily single mothers, who began using opioids in their teens. It should also be noted that some of our younger participants presented with histories of abusing prescription opioids much earlier in the progression of their use, and this is consistent with growing reports of prescription opioids becoming the new gateway drug (Mars, Bourgois, Karandinos, Montero, & Ciccarone, 2014).

It is interesting that over half of our group members presented at the time of intake with UDS that were positive for buprenorphine. They would often indicate that they switched from their opioid drug of choice to buprenorphine or buprenorphine/naloxone when they discovered they were pregnant because they heard it was "safer." They were also aware that pregnancy made them eligible for a medical card and that the card covered treatment with buprenorphine (unlike methadone). Increased lay knowledge about buprenorphine and reductions in barriers to treatment with regard to insurance coverage are notable in regard to the need for increased access to treatment for pregnant women.

Ours is one of the few studies to specifically investigate the impact a homogeneous pregnancy group may have on treatment retention and outcomes. Both therapy groups incorporated CBT, psychoeducation on the disease model of addiction, relapse prevention, and 12-step facilitation components. In addition, once every six to eight weeks OBGYN-affiliated providers co-led the pregnancy group and discussed pregnancy- and birth-related topics such as labor and delivery, pain control at delivery, NAS, breastfeeding, and birth control. Anecdotally, the group therapist experienced a higher level of cohesion and trust among the participants in the pregnancy-only groups, although this was not captured on satisfaction survey data, nor did it translate into significant difference in retention rates. Pregnancy-only group members were less likely to relapse, though given that this pilot study was underpowered, the difference was not statistically significant. Even without prescribed content differences, the increased freedom to discuss pregnancy-related issues, share delivery experiences, and bring their babies into group made a distinct difference in the two groups' experiences. The pregnancy-only group participants seemed more connected as evidenced by contact and social support provided to one another outside of group and the strong desire they expressed not to change groups once they had delivered. Further anecdotal evidence of social networking facilitated by the groups included group members helping one another problem solve transportation and child care issues, which are often gender-specific barriers to treatment for women. In addition, two potential group members refused to participate in the study at the outset because they preferred to be in the pregnancy-only group and could not be guaranteed that due to the randomization process.

Despite the retention rates for both groups being approximately 50%, it should be noted that nearly one-quarter of those women were referred to a higher level of care. Given the severity of substance abuse histories and high incidence of comorbid psychiatric diagnoses, this should not be interpreted as treatment failure. A once-a-week therapy intervention and participation in four 12-step meetings weekly for patients who have been abusing substances for many years is often not intensive enough. Even in situations where noncompliance was an issue, attempts were made to direct women to other programs such as methadone clinics. It is unknown how many of those remained in some form of treatment. Many of our participants expressed a concern about losing their medical card not long after delivery. We suspect this may be a reason some patients failed to continue to attend postpartum.

The results regarding the quality-of-life measure were concerning given that the majority of participants in each group reported either no change or a decrease in their quality of life at four weeks postpartum. It is possible that four weeks postpartum is not an optimal time to measure quality of life for a young single parent with low SES regardless of any substance abuse history. The low quality-of-life score is also of particular concern because many of our participants expressed a desire to taper off buprenorphine after delivery due to a combination of internal and external motivators, yet it is not uncommon to see relapses occur during this period. Pregnant and postpartum women with mood disorders and multiple psychosocial stressors are known to be at increased risk for relapse (Fitzsimons, Tuten, Vaidya, & Jones, 2007).

The results of the satisfaction survey data indicated no significant differences between the intervention group and TAU in areas of feeling accepted by the therapist and other group members, comfort in participating, and ratings of patient–therapist relationship. There was, however, a difference with regard to the relevance of topics discussed at week 4 and week 8 of treatment. The pregnancy-only group reported

significantly higher rates of topic relevance, which could potentially result in more positive outcomes. Having pregnancy-related discussions co-led by affiliated OBGYN providers may have contributed to the significant difference in topic relevance. This different became insignificant by 12 weeks, which could indicate that once patients are engaged in treatment, topic relevance becomes less important than in the early stages of treatment. Although not part of the study, having increased interaction between OBGYN-affiliated staff and the group therapist led to collaborative relationships and nursing education that continued after the study ended.

We did not seek to study the incidence of NAS directly, but as part of the protocol we did review the medical records of the neonates delivered by our patients. Of the 22 babies we were able to collect data on, 23% required treatment for NAS. One of the criticisms of medication-assisted treatment with buprenorphine is the reported high rates of NAS. Our rates are much lower than those in previous studies of infants born to mothers on buprenorphine (Fischer et al., 2006; Johnson, Jones, & Fischer, 2003; Jones et al., 2010). Average dose of buprenorphine among the 45 women was 12 mg.

Limitations of the study include the low number of participants who actually completed the study (only half of those consented), therefore limiting our ability to determine statistical significance among our primary dependent variables of retention and relapse rates. In addition, the explicit content of the OBGYN-affiliated providers' group discussion was not structured, nor were satisfaction ratings administered specific to these group sessions. Perhaps if this portion of the intervention were more prescribed it would have added to the efficacy of the intervention, and the impact could have been more explicitly measured and replicated. It also may have been of benefit to have the group therapist rate the groups on measures of cohesion as an additional way to measure difference between the two group interventions. We attempted to capture end-of-study feedback from each participant to gather more qualitative data, which may have helped to shed light on some of the differences experienced by the participants; however, this measure was not consistently administered due to logistical reasons.

In retrospect, the QOLI data ended up not measuring what it was intended to measure due to the timing of when the survey was administered. Four weeks postpartum is often a very stressful time for any woman and did not reflect the gains participants made in treatment as was hoped. In future research, administering this survey should occur approximately one month prior to delivery rather than after.

CONCLUSION AND SCIENTIFIC SIGNIFICANCE

The treatment of opioid dependence in pregnancy is a significant topic of concern from both the individual and the systems perspectives, and there is much we need to learn about effective treatment. The goal of this study was to add to the knowledge relevant to developing standards of care for outpatient medication-assisted treatment with buprenorphine in this population by comparing TAU with pregnancy-only group interventions. Our initial hypothesis was that a pregnancy-only group would be superior to TAU in terms of retention in treatment, lower rates of relapse, patient satisfaction, and quality-of-life measurements. Our findings suggest that the two groups were very similar on all measures. To better test the hypothesis, future research with a larger sample size would be required. It is important to note that the pregnancy-only group was at least comparable in efficacy to the mixed-gender group and that by offering pregnancy-only groups, treatment settings can increase the availability and access pregnant women have to services. From this study, it appears that one of the most important factors in managing pregnant patients with opioid use disorders is to reduce barriers to treatment and treat the opioid dependence itself. The 23% incidence of NAS in our population is noteworthy and adds to the evidence that withdrawal is less severe among babies born to mothers on buprenorphine.

Pregnant women with SUDs are among our most vulnerable populations. Developing evidence-based treatments that integrate their biopsychosocial needs and foster mutual support while facilitating interdisciplinary communication among providers is paramount for both the improved health of the mother and the unborn child. SWR

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