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Perinatal Mortality and Adverse Pregnancy Outcomes in a Low-Income Rural Population of Women who Smoke

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SUMMARY

We describe adverse pregnancy outcomes, including congenital anomalies, fetal, neonatal, and infant mortality among a Missouri population of low-income, rural mothers who participated in two randomized smoking cessation trials. In the Baby Beep (BB) trial, 695 rural women were recruited from 21 WIC clinics with 650 women's pregnancy outcomes known (93.5% retention rate). Following the BB trial, 298 women, who had a live infant after November 2004 were re-recruited into and completed the Baby Beep for Kids (BBK) trial. Simple statistics describing the population, perinatal and postneonatal mortality rates were calculated. Of the adverse pregnancy outcomes (n=79), 29% were spontaneous abortions of <20 weeks gestation, 23% were premature births and 49% were identified birth defects. The perinatal mortality rate was 15.9 per 1,000 births (BB study) compared to 8.6 per 1,000 births (state of MO) and 8.5 per 1,000 births (U.S.) The postneonatal infant mortality rate was 13.4 per 1,000 live births (BBK) compared to 2.1 per 1,000 live births (U.S.). The health disparity in this population of impoverished rural pregnant women who smoke, particular with regard to perinatal and infant deaths, warrants attention.

INTRODUCTION

Congenital anomalies, preterm birth, and low birth weight are leading causes of infant mortality in the US, accounting for 36% of all infant deaths in 2005 (Mathews and MacDorman 2008). It was thought that rural residency conferred less risk of adverse pregnancy outcomes; therefore, maternal health research has mostly been conducted in urban settings (Hillemeier et al. 2007). However, an increasing number of studies have reported a higher incidence of congenital anomalies and perinatal deaths in rural compared to urban populations (Baldwin et al. 2002; Bell et al. 2001; Cardwell and Gay 1990; Druschel and Hale 1987; Hillemeier et al. 2007; Langlois et al. 2009; Larson et al. 1997; Luo et al. 2008; Schreinemachers 2003; Schwartz et al. 2000). Despite such findings, very little research has examined such outcomes among rural pregnant women. In addition,

national-level data is based upon birth and death certificates and thus overlooks important pregnancy outcomes such as fetal deaths prior to 20 weeks (Mathews, 2008). In this paper, we begin to address this gap by describing adverse outcomes, including congenital anomalies, fetal, neonatal, and infant mortality among a population of low-income, smoking, rural mothers who participated in two large randomized smoking cessation trials.

METHODS

Study Population

These data represent an analysis from two longitudinal randomized controlled trials of women who smoked during pregnancy: Baby BEEP (Bullock, PI NIH: NR05313) and Baby BEEP for Kids (Bullock, PINIH: HD045542). The Baby BEEP trial has been previously reported using CONSORT guidelines (Bullock et al. 2009) and the other trial is in data analysis phase. The Baby BEEP (BB) trial consisted of 695 women recruited from 21 rural WIC services (Women, Infant, and Children Nutritional Program) clinics in the state of Missouri between January 2002 and September 2005 with deliveries beginning in 2002 and ending in 2006. All participants received WIC through documenting income at or below 185% of the US poverty income guideline. In addition, to be eligible for the BB study, women were 18 years or older, < 24 weeks pregnant, spoke English, and reported smoking at least one cigarette daily. A sub-set of women from the BB trial (N = 325) who delivered a live infant after November 2004 were eligible and re-recruited for the Baby Beep for Kids (BBK) trial. This trial followed these mothers and infants for an additional two years between December 2004 and September 2008. Both studies were approved by the University of Missouri Health Sciences Institutional Review Board and the Missouri Department of Health and Senior Services. Written consents for both studies were obtained from participants.

As part of the BB trial, which involved a nurse-delivered telephone social support smoking cessation intervention, (Bullock et al. 2009) all women's smoking behavior was monitored monthly by collecting saliva biospecimens to test for cotinine, a by-product of nicotine at an in person visit with a study nurse in the participant's home or convenient location. This frequent contact with the women provided the opportunity to closely follow outcomes of the pregnancy. In addition, all women were interviewed by research nurses using a series of questionnaires at baseline, at 28–32 weeks gestation, and at 6-weeks post-delivery (Bullock et al. 2009). At the post-delivery interview, women were asked general questions about the birth of the baby, such as date, infant weight, infant height and if the baby had been seen by a health care provider or diagnosed with any congenital conditions. If the mother answered in the affirmative regarding an abnormality, the nurse-interviewer asked for the diagnosis. From this question, a number of congenital anomalies were uncovered.

The Baby BEEP for Kids (BBK) trial assessed infants for growth and neurodevelopmental outcomes at 6, 15, and 24 months post-delivery through home visits to test the child. Additionally, the mothers were asked if the baby had been diagnosed with any health issues since the last visit. If the mother responded in the affirmative, the nurse-interviewer asked for details. This second trial allows us to report on infant deaths and/or congenital anomalies not obvious during the neonatal period.

Measures

Demographic data collected at the beginning of the BB trial included maternal age, education, race/ethnicity, and the number of previous live births. Additionally, valid and reliable measures were used to measure psychosocial variables, parenting stress and smoking status throughout the two trials (Bullock et al. 2009). Of interest to this paper is maternal stress, measured via the Prenatal Psychosocial Profile (PPP).

The PPP consists of three sub-scales measuring stress, social support and self-esteem. The stress subscale is an 11-item Likert Scale of perceived stress on a scale of 1 to 4 (1=no stress, 2=some stress, 3=moderate stress, 4=severe stress), on a range of items from financial stress to problems with the family. Higher scores on this subscale indicate greater perceived stress. The PPP has been widely used and has been shown to be a reliable and valid measure of stress, social support and self-esteem (Curry et al. 1998).

Statistical Analyses

Standard definitions were used to determine fetal, neonatal, perinatal, and postneonatal infant mortality rates. Fetal deaths were defined as intrauterine deaths at any gestational age and can be termed as early (<20 weeks gestation) middle (20–27 weeks gestation) or late (>27 weeks gestation) depending on gestational age. Neonatal death was defined as a live birth followed by death of the infant at ≤ 28 days of age. The CDC (MacDorman and Kirmeyer, 2009) more inclusive definition for determining birth outcomes is the perinatal mortality rate. Perinatal deaths referred to any fetal deaths of ≥ 20 weeks gestation plus all neonatal deaths. Infant death, by definition, includes both neonatal and postneonatal deaths; but to be eligible for the BBK study, a woman had to have a live infant at the 6-week post-partum interview. Those women whose infant died before the 6-week interview were not eligible to participate in the BBK study. National Vital Statistics Reports (NVSS) data was based upon birth and death certificates and thus included only fetal deaths of ≥ 20 weeks gestation (Mathews and MacDorman 2008). For direct comparison with such data, we provided a perinatal mortality rate from our study. This was calculated using total number of fetal deaths ≥ 20 weeks gestation and neonatal deaths as the numerator; the denominator (n = 627) was all participants enrolled in Baby BEEP whose pregnancy outcome was known minus the women who aborted their fetus before 20 weeks gestation. In addition, the nature of our data allowed us to report a more comprehensive mortality rate, which included ALL fetal deaths prior to 20 weeks which is even more inconclusive than the CDC perinatal mortality rate because our close monitoring of the women on a monthly basis allowed us to know who had early spontaneous abortions. This second more inclusive perinatal mortality rate (“BB perinatal mortality rate”) was calculated using all women who had early (< 20 weeks gestation), middle (20–27 weeks gestation) or late (>27 weeks gestation) fetal death or neonatal death as numerator and denominator was all participants enrolled in Baby BEEP whose pregnancy outcome was known (n = 650).

Analyses used simple statistics (frequencies, mean and standard deviations) to describe the sample. Pearson’s Chi-square test (and Fisher’s exact test, when appropriate) was used to test whether those with adverse pregnancy outcomes compared to those with unaffected birth outcomes varied by participant characteristics.

RESULTS

Of the 1420 referrals from 21 WIC clinics, 488 were ineligible (278 not meeting eligibility requirements: (at least 18 years old, <24 weeks pregnant, English speaker, reported smoking at least 1 cigarette day) and 210 unable to locate) and therefore were not recruited. Of the 932 potential participants, 237 declined participation and 695 were enrolled in the study (participation proportion of 65.6%) (Druschel and Hale 1987). Birth outcomes were known for 650 participants in the Baby Beep cohort (93.5% retention rate). The remaining 45 participants either ended participation during the pregnancy or were lost to follow-up. Of these 650 BB participants, 325 women and their babies were re-recruited into in the BBK trial. Of these 325 women, 27 participants ended participation or were lost to follow up. Those lost to follow-up were similar to the full dataset (data not shown). Thus, for the BBK postneonatal infant mortality rate, data from 298 participants were used in our calculations. The sample of rural, low-income women in this study of 650 women was primarily young, white, and of relatively low education (Table 1). The mean estimated gestational age at mother's enrollment was 13.9 weeks (s.d. 4.5) with 85% of the participants enrolling at less than 20 weeks of baby's gestational age. Many characteristics of women who had unaffected babies (n=571) were similar to those who had an adverse pregnancy outcome (n = 79), including distribution of age at enrollment, race and ethnicity, marital status, stress levels, maternal smoking, and parity (Table 1). Women, age 25 years and older with adverse pregnancy outcomes, were more likely to have education beyond high school graduate (50%) compared to women with unaffected babies (24%).

Of the 79 adverse birth outcomes over our study period (2002–2008), 28% were spontaneous abortions of less than 20 weeks gestation, 23% were premature births and 49% were identified birth defects (Table 2). Of the congenital anomalies, approximately half were either heart defects (28%) or genetic abnormalities (19%). Examples of the known defects included Tetralogy of Fallot, chromosomal anomalies (e.g., Downs, Cri-du-Chat and enzyme deficiencies), and structural defects (e.g., imperforate anus, club feet, and cleft lip/palate). In our population (n=627), the prevalence of identified congenital anomalies (n = 36) was 574.2 per 10,000 births (Table 2).

The perinatal mortality rate (fetal deaths > 20 weeks gestation plus neonatal death up to 28 days post-delivery) for the BB study was 15.9 per 1,000 births (95% CI: 7.4 – 28.1 per 1000 births). The more inclusive BB perinatal mortality rate that includes all intrauterine fetal deaths regardless of gestational age plus neonatal deaths (denominator = 650) was 50.8 per 1,000 births (95% CI: 35.2 – 70.6 per 1000 births). The postneonatal infant mortality rate for women who participated in the BBK trial was 4 deaths out of 298 consented women (13.4 per 1,000 live births; 95% CI: 3.7 – 34.0 per 1000 live births).

DISCUSSION

Although low SES, maternal smoking, and rural residence are known risk factors for adverse outcomes, much of the evidence has come from review of birth and death certificates (Druschel and Hale 1987; Hillemeier et al. 2007; Johansson et al. 2009; Salihu et al. 2003). Further, to our knowledge none have longitudinally studied a population specifically

comprised of these three risk factors. Our study indicated that for these women, the likelihood of losing a baby may be much higher than the average pregnant woman whereas having a baby with some type of abnormality is about the same as any other woman. Specifically, the congenital anomaly rate is 574.2 per 10,000 in the BB population compared to the state rate for non-Hispanic white women is 557 per 10,000 (Dunn et al. 2003). In contrast, the perinatal mortality rate that includes both fetal deaths 20 weeks gestation and all neonatal deaths was 15.9 per 1000 pregnancies. This is nearly double the rate for non-Hispanic White women reported in Missouri in 2006 of 8.6 per 1000 (MICA 2009) and nationally (8.5 per 1000 8.5 per 2005 data) (Mathews and MacDorman 2008). As noted in table 2, the majority of perinatal deaths with a known diagnosis, reported by the mother to the study staff, were related to heart defects (36%) or prematurity (36%). In contrast, the 4 infant deaths reflected greater variability in cause (SIDS, chromosomal abnormality, gastrointestinal abnormality).

Perinatal mortality is an important indicator of population health. However, infant mortality is commonly used in the literature. Although the comprehensive, longitudinal nature of this study allowed us to determine outcomes for infants up to two years, we are only able to report the postneonatal infant death rate because women must have had a live infant at 6 weeks post-delivery in order to be eligible to participate in the second trial. Thus, eligibility for BBK excluded women whose infant may have died in the first 28 days of life. Our postneonatal infant mortality rate, without any infants who died in the first 28 days of life, was (13.4 per 1000). This is more than double compared to the US infant mortality rate for non-Hispanic White women (5.7 per 1000 5.7 per 2005 data) (Mathews and MacDorman 2008) and this rate includes both the neonatal period (3.7 per 1000) and postneonatal period (2.1 per 1000) (Mathews and MacDorman 2008). Our study suggests a significant maternal-child health disparity among this group of low-income, rural smoking mothers.

The mechanisms which produce such disparities are poorly understood, and more research is needed. Given the diversity of adverse pregnancy outcomes, it is unlikely that a single mechanism explains the heterogeneity in adverse pregnancy outcomes. However, certain risk factors previously described in the literature— rural residency, maternal smoking, maternal stress, and maternal socioeconomic status – may be important factors in understanding the risks faced by rural, smoking, low income women, and research using a multifactorial model warrants future investigation. We briefly describe these risk factors below.

Rural residency

Improving maternal-child health is one of the top ten priorities in the Rural Healthy People 2010 goals (Gamm et al. 2003). Health disparities research has most often focused on rural access to care or excluded rural residents altogether (Center for Rural Health Practice 2004). However, rural women may face higher risk of adverse pregnancy outcomes (Baldwin et al. 2002; Bell et al. 2001; Cardwell and Gay 1990; Druschel and Hale 1987; Hillemeier et al. 2007; Langlois et al. 2009; Larson et al. 1997; Luo et al. 2008; Schreinemachers 2003; Schwartz et al. 2000

Smoking

Addressing tobacco use is another of the top ten priorities in the Rural Healthy People 2010 goals (Gamm et al. 2003). Smoking during pregnancy is linked to a higher risk for infant death (Salihu et al. 2003). Eligibility criteria for the BB study included smoking at least one cigarette daily during early pregnancy. Our study did not show any statistically significant difference in fetal deaths based on reported smoking levels at two time points: during the first or second trimester.

Stress

Maternal stress as an etiologic factor in maternal-child health outcomes is receiving increased research attention (Hobel 2004; Rich-Edwards and Grizzard 2005; Wadhwa et al. 2001). The majority of maternal stress research has been conducted in urban settings (Hodnett and Fredericks 2003). However, women in rural areas may face unique stressors e.g., increased isolation, lack of transportation and healthcare, and socioeconomic vulnerability (Gamm et al. 2003). In the limited data available, rural women report substantial levels of stress (Bhandari et al. 2008; Hillemeier et al. 2004; Weisman et al. 2006).

In the present study, our measure of stress via the PPP was not significantly different between women who had adverse pregnancy outcomes, compared to those who did not. Stress is a multidimensional concept, and measurement of maternal stress is extremely complex (Hobel 2004; Hogue et al. 2001) and it may be that the PPP failed to capture dimensions of maternal stress among this sample that were salient to this research question.

Socioeconomic status

All of the mothers in this sample were also of low socioeconomic status (SES), and thus the unique contribution of maternal SES to their adverse outcomes cannot be fully assessed in this study. However, the literature suggests that SES likely contributed to their risk for adverse outcomes (Hogue et al. 2001; Kramer et al. 2001; Rich-Edwards and Grizzard 2005). High infant mortality among this low-income, relatively low-educated rural sample adds to the body of evidence regarding SES and adverse pregnancy outcomes. Long-term low SES appears to adversely affect health, suggesting a “dose-response” relationship between SES and health (Geronimus 2000). However, little data explores the influence of chronic low SES on maternal health. Even less research explores these relationships among rural populations.

Participating mothers were enrolled in the WIC program, (Women, Infant, and Children Nutritional Program) which represents women of low economic status. One of the primary services provided by the WIC program is nutrition education and counseling as well as supplemental food provided at no cost to the participants. A medical evaluation of the supplemental food program in WIC program reported improved diets of pregnant women through increased protein, minerals and several vitamin (Edozien, 1979). Swensen et al evaluated the WIC program and noted 83% of WIC women took prenatal vitamins, although compliance could not be determined (Swensen, 2001). However, consistent findings have shown WIC participants have shown that adequate consumption of iron was the most

notable dietary efficient. (Edozien, 1979; Swensen, 2001). These variables were not measured in the current study and a limitation of our findings.

Another limitation of our findings is that we relied on maternal reported information about pregnancy outcomes. It is unlikely that mothers who reported any health issue with their babies to their health providers did not share this information with our study staff. However, it is possible that some health problems were either not recognized by the mother or possibly not reported to either the health provider or our study staff. Consequently, our rates may reflect the lower limit in this group of women. Conversely, we used mother's report of their baby's health, including congenital abnormalities without verification through medical record abstraction or physical examination of the child. Congenital abnormalities may have different risk factors than explored in our paper and therefore the mortality associated with the discussed risk factors may be an overestimation. Another limitation is the timing of enrollment. The majority of women (85%) were enrolled prior to an estimated baby's gestation of 20 weeks. The choice of denominator in calculating the mortality rates was conservative in that we included all women at risk for an adverse pregnancy outcome regardless of time of enrollment. Although the 97 women enrolled after an estimated baby's gestation age of 20 weeks were not at risk for having an early or middle spontaneous abortion, they were at risk for fetal, neonatal and infant death. Therefore including these women in the denominator for calculating perinatal mortality rates, in effect, potentially reduced the perinatal mortality rate. Likewise, women who had early spontaneous abortions were not enrolled in the study and not included in our rates. Selection bias could have influenced our findings. Due to the study design of enrolling low income rural women who were smokers, we were unable to evaluate the influence of these risk factors on adverse pregnancy outcomes since we had no comparison group. Lastly, a limitation of our findings is the small number of adverse outcomes. These outcomes were observed over several years thus limiting comparisons that can be made to national and state yearly rates. However, our study did show that this population faced considerable risk of an adverse pregnancy outcome, especially death of their infants compared to the average pregnant woman and our findings warrant further research, particularly since little research has been done with rural women.

One strength of our findings is that women in the BB study were followed closely throughout their pregnancy, and a subset were followed for an additional 24 months post-delivery in BBK, thus detailed longitudinal data is available. Retention was extremely high for both the Baby BEEP and Baby BEEP for Kids trials (93.2% and 92.0%, respectively), and the few lost to follow-up did not appear to differ significantly from those who remained, adding additional confidence in the findings. Further, unlike available vital statistics data which captures adverse outcomes after 20 weeks of gestational age, we were able to document fetal deaths occurring prior to 20 weeks gestation in our cohort of women.

Conclusion

The results from two longitudinal, randomized controlled trials of low-income, rural pregnant women who smoked during pregnancy add to the very limited knowledge base regarding adverse pregnancy outcomes in this population. Infant mortality data is a strong

indicator of the health of a population, and the significant health disparities in infant mortality continue to exist among racial minority women in the US (Hogue and Vasquez 2002). The data from this study suggest that these women may be particularly vulnerable to perinatal and postneonatal infant mortality, particularly if they smoke and are of low SES. Rural populations are unique, (Center for Rural Health Practice 2004) and a better understanding of how risk factors for adverse pregnancy outcomes intersect with SES among pregnant women, including the influence of stress and maternal smoking, and what interventions are most effective in this population to improve pregnancy outcomes is needed. Further perinatal interventions need to be improved to decrease risk among the most vulnerable women in rural communities.

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Characteristics of Baby Beep Participants by Pregnancy Outcome and Available Data on 2005 Births of Missouri Residents

Table 1

Characteristics	All Baby Beep Participants (n=650)		Baby Beep Participants w/ Healthy Babies (n=571)		Baby Beep Participants w/ Adverse Pregnancy Outcome (n=79)		p-value ^c	2005 Births of Missouri Residents (n=78,540) ^d	
	Number	Percent	Number	Percent	Number	Percent		Number	Percent
Mother's Age at Enrollment							0.12		
<21	150	23%	135	24%	15	19%		8707	11%
20–24	310	48%	276	48%	34	43%		22,800	29%
25–29	124	19%	106	19%	18	23%		22,693	29%
30–34	44	7%	36	6%	8	10%		15,904	20%
35	22	3%	18	3%	4	5%		8436	11%
Race and Ethnicity							0.21		
White/European American	591	91%	519	91%	72	91%		64,136	82%
Black/AfroAmerican	23	4%	17	3%	6	8%		11,455	15%
Latino/Hispanic	10	2%	9	2%	1	1%		4,264	5%
Asian American	2	<1%	2	<1%	0	0%		1,739	2%
Native American	10	2%	10	2%	0	0%		426	<1%
Other	14	2%	14	2%	0	0%		350	<1%
Number of years of education (in years) ^a							0.01		
Less than 12	77	41%	71	44%	6	20%		14,357	18%
12 years	60	32%	51	32%	9	30%		24,085	31%
12.5 – 15 years	47	25%	33	21%	14	47%		18,127	23%
16 or more years	6	3%	5	3%	1	3%		21,146	27%
Parity									
1	183	28%	157	28%	26	33%	0.73		
2	105	16%	91	16%	14	18%			
3 or more	66	10%	58	10%	8	10%			
nulliparous	296	46%	265	46%	31	39%			
Marital status							0.67		
Married	457	70%	403	71%	54	68%		48,853	62%
Not married	192	30%	167	29%	25	32%		29,669	38%

Characteristics	All Baby Beep Participants (n=650)		Baby Beep Participants w/ Healthy Babies (n=571)		Baby Beep Participants w/ Adverse Pregnancy Outcome (n=79)		p-value ^c	2005 Births of Missouri Residents (n=78,540) ^d	
	Number	Percent	Number	Percent	Number	Percent		Number	Percent
Smoking before pregnancy ^b							0.58		
None	0	0%	0	0%	0	0%			
1–10 (up to 1/2 pack)	96	15%	81	14%	15	19%			
11–20 (1/2 to 1 pack)	300	46%	268	47%	32	41%			
21–30 (1 to 1–1/2 pack)	179	28%	157	28%	22	28%			
31 or more (more than 1–1/2 pack)	75	12%	65	11%	10	13%			
Smoking at baseline [†]							0.54		
None	8	1%	7	1%	1	1%			
1–10 (up to 1/2 pack)	394	61%	351	61%	43	54%			
11–20 (1/2 to 1 pack)	213	33%	181	32%	32	41%			
21–30 (1 to 1–1/2 pack)	32	5%	29	5%	3	4%			
31 or more (more than 1–1/2 pack)	3	<1%	3	<1%	0	0%			
Perinatal Psychosocial Profile--Stress subscale									
Mean (standard deviation)	21.8	s.d. 5.1	21.8	s.d. 5.1	21.7	s.d. 4.6			

^a education level for those 25 years or older^b self-reported smoking levels^c determined using Chi-square or Fisher exact test, as appropriate^d Missouri Department of Health and Senior Service Birth MICA data

Description of Adverse Pregnancy Outcomes and Medical Conditions of Infants from Baby BEEP study (n=695)^a and Baby Beep for Kids (n=298)^c**Table 2**

Birth condition (2002–2005)	Birth Outcome ^b	Early Spontaneous Abortion (<12 weeks gestation)	Middle Spontaneous Abortion at 12–20 weeks gestation	Fetal Deaths at > 20 weeks gestation	Neonatal Deaths	Infant Deaths ^c
Healthy	570	-	-	-	-	1
Adverse pregnancy outcome						
Premature	18	-	-	4	-	-
Heart Defect	11	-	-	1	3	-
Genetic Abnormality	7	-	-	-	-	1
Gastrointestinal	5	-	-	-	-	1
Other	5	-	-	-	1	2
Spontaneous Abortion	22	13	9	-	-	-
Genito-urinary	3	-	-	-	1	-
Respiratory	3	-	-	-	-	-
Central Nervous System	2	-	1	-	-	-
Muscular-skeletal	2	-	-	-	-	-
Oral-Respiratory	1	-	-	-	-	-
Total	79	13	10	5	5	5

^a gestation age calculated from mother's reported last menstrual period^b Of the 695 participants, 650 participant's birth outcomes are known^c Cohort of Baby BEEP participants into Baby BEEP for Kids: 298 mothers and infants