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Pregnancy outcomes and ethanol cook stove intervention: A randomized-controlled trial in Ibadan, Nigeria☆

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ABSTRACT

Background: Household air pollution (HAP) exposure has been linked to adverse pregnancy outcomes.
Objectives: A randomized controlled trial was undertaken in Ibadan, Nigeria to determine the impact of cooking with ethanol on pregnancy outcomes.
Methods: Three-hundred-twenty-four pregnant women were randomized to either the control (continued cooking using kerosene/firewood stove, n = 162) or intervention group (received ethanol stove, n = 162). Primary outcome variables were birthweight, preterm delivery, intrauterine growth restriction (IUGR), and occurrence of miscarriage/stillbirth.
Results: Mean birthweights for ethanol and controls were 3076 and 2988 g, respectively; the difference, 88 g, (95% confidence interval: −18 g to 194 g), was not statistically significant (p = 0.10). After adjusting for covariates, the difference reached significance (p = 0.020). Rates of preterm delivery were 6.7% (ethanol) and 11.0% (control), (p = 0.22). Number of miscarriages was 1(ethanol) vs. 4 (control) and stillbirths was 3 (ethanol) vs. 7 (control) (both non-significant). Average gestational age at delivery was significantly (p = 0.015) higher in ethanol-users (39.2 weeks) compared to controls (38.2 weeks). Perinatal mortality (stillbirths and neonatal deaths) was twice as high in controls compared to ethanol-users (7.9% vs. 3.9%; p = 0.045, after adjustment for covariates). We did not detect significant differences in exposure levels between the two treatment arms, perhaps due to large seasonal effects and high ambient air pollution levels.
Conclusions: Transition from traditional biomass/kerosene fuel to ethanol reduced adverse pregnancy outcomes. However, the difference in birthweight was statistically significant only after covariate adjustment and the other significant differences were in tertiary endpoints. Our results are suggestive of a beneficial effect of ethanol use. Larger trials are required to validate these findings.

1. Introduction

Household air pollution (HAP) from the burning of biomass is the eighth leading contributor to overall global disease burden (Forouzanfar et al., 2016). As a major public health hazard that disproportionately affects nearly three billion people (predominantly women and children) living in developing countries, HAP poses a significant barrier to achieving health equity. In 2015, HAP was estimated to have caused approximately 2.9 million premature deaths and 85 million disability-adjusted life years (DALYs) globally (Forouzanfar et al., 2016).

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In Africa, biomass fuels are the primary energy source used for cooking in approximately 81% of households (Sander et al., 2011). Within Nigeria, an estimated 70% of the population uses solid fuels (Desalu et al., 2012; Ezeh et al., 2014), and up to 27% use kerosene (Ibitoye, 2013) for household energy needs. According to Nigeria Demographic and Health Survey records from 2013 (NDHS, 2013; Samuel et al., 2016), 26% of the Nigerian households (48% of urban households and 9% of rural households) use kerosene. Consequently, high levels of health-damaging pollutants such as particulate matter (PM), carbon monoxide (CO), and polycyclic aromatic hydrocarbons (PAH) emitted from incomplete combustion of these fuels threaten the health of vulnerable populations and worsen global environmental degradation (Ezeh et al., 2014; Lam et al., 2012; Naeher et al., 2007).

PM levels from incomplete combustion of cooking fuels can far exceed World Health Organization (WHO) indoor air quality guidelines (IAQGs) (WHO, 2014). The health impacts of HAP exposure for women and children include respiratory, cardiovascular, and ocular damage (Ezzati and Kammen, 2002). Nigeria, in particular, is one of the sub-Saharan countries where HAP is associated with high preventable mortality and DALYs (Forouzanfar et al., 2016).

Ambient air pollution (AAP) (Lacasana et al., 2005; Sapkota et al., 2012), HAP (Mishra et al., 2004; Thompson et al., 2011), active maternal smoking, and exposure to environmental tobacco smoke (Andres and Day, 2000) have been widely associated with adverse pregnancy outcomes such as first trimester miscarriages, low birthweight (LBW), preterm births, intrauterine growth restriction (IUGR), and decreased fetal head circumference. High levels of ambient $PM_{2.5}$ (PM $<$ 2.5 μm in diameter) are significantly associated with lower infant birth weight (Morello-Frosch et al., 2010). Premature delivery risks have been shown to significantly increase with exposure to ambient PM, but reported levels of PM concentrations in previous research are substantially lower than in homes using biomass fuels (Ritz et al., 2007). Similar adverse health impacts have been seen with exposure to kerosene (Epstein et al., 2013; Lakshmi et al., 2013).

Similarly, HAP exposure from household cooking has been associated with adverse pregnancy outcomes (Amegah et al., 2014; Pope et al., 2010; Siddiqui et al., 2008), but much of the prior research on this topic has been cross-sectional and does not demonstrate clear causation. Currently, there are few groups conducting randomized controlled cookstove intervention studies to investigate birth outcomes, child survival and respiratory illness in children and blood pressure changes during pregnancy in women (Jack et al., 2015; Mortimer et al., 2017; Quinn et al., 2017; Tielsch et al., 2014). Yet, it is important to quantify the impacts of these exposures and evaluate practical solutions to reduce exposures to HAP. This randomized, controlled trial (RCT) was conducted in order to compare pregnancy outcomes in women exposed to HAP from wood and kerosene-fueled cookstoves in Ibadan, Nigeria to those in women who received ethanol CleanCook stoves (which meet tier 4 for indoor emissions performance standards based on the framework in the International Organization for Standardization's (ISO) Interim Workshop Agreement (IWA) Guidelines for evaluating cookstove performance (ISO, 2012). We hypothesized that this cookstove intervention would reduce exposure to $PM_{2.5}$ for pregnant women and improve pregnancy outcomes.

2. Methods

2.1. Study design

Between June 2013 and October 2015, a RCT was conducted with 324 pregnant women living in Ibadan, a Nigerian city of over three million; the population in this area is predominately Yoruba. Pregnant women were screened for eligibility at time of presentation at one of three primary health care centers (PHCs) within urban or peri-urban areas of Ibadan. These PHCs - Agbongbon, Oranyan, Ijaye, and Olorishaoko - are host to approximately 600, 750, 100, and 50 births per year, respectively. The study protocol was approved by ethical review boards at the University of Ibadan and the University of Chicago (UC) and is registered with ClinicalTrials.gov (NCT02394574). The primary outcomes of interest for this study were birthweight, preterm delivery, IUGR and occurrence of miscarriage or stillbirth. IUGR and other ultrasound assessments of fetal growth are the subject of a separate paper (in preparation). Exposure levels were secondary outcome variables. Tertiary endpoints included gestational age (GA), Apgar scores, placental weight, birth length, head circumference, respiratory rate, neonatal death, birth defects, and perinatal mortality (stillborn or neonatal death).

2.2. Subject recruitment

Women who presented at any of the PHCs for antenatal care and were less than or equal to 18 weeks pregnant, determined by ultrasound biometry, were eligible to participate. Additionally, they had to already be using either wood burning or kerosene stoves as their primary cooking fuel. Individuals were excluded if they were HIV positive, smokers, lived with a smoker, cooked for a living, or had a high-risk pregnancy (defined as pregnancy with multiple gestations, uncontrolled maternal hypertension, maternal age $>$ 35 for first delivery, three or more prior miscarriages, or prior Cesarean-section).

2.3. Enrollment and randomization

When first presenting to an eligible PHC, interested women were given a detailed description of the study and participation requirements and a summary of associated risks. Consenting women were then evaluated against the inclusion and exclusion criteria listed above.

Those that met all criteria were individually randomized to the ethanol or control arm using the web-based randomization module in REDCap (Harris et al., 2009). Randomization was stratified by parity ($<=4$ vs. >4 children) and the presence or absence of diabetes. Treatment assignments were prepared in advance by the study biostatistician using the method of permuted blocks (Matts and Lachin, 1988) Of the 324 women enrolled, 162 were assigned to the ethanol-stove group. Women in this group were given a CleanCook ethanol stove (CLEANCOOK Sweden AB) and an initial supply of fuel at the first home visit, which occurred between 16–18 weeks GA. During this visit, comprehensive training regarding the dangers of smoke exposure and the proper use of the stove was provided. Additionally, field workers observed each woman refill, light, and use the stove for the first time. Women randomized to the control group (n = 162) continued to use their original firewood or kerosene stoves. Each woman in this group was also given training and a poster that had information on the dangers of smoke exposure and how to reduce their exposure to smoke while cooking. The ethanol used in the study was imported and secured through support from Shell Exploratory Company. Shell had no input or contribution to the study design and implementation beyond the contribution of about 50,000 l of ethanol.

2.4. Data collection

A detailed breakdown of the study flow and the timing of data collection are depicted in Fig. 1. Data collection began at the PHCs after interested, eligible women gave informed consent. At this first visit, interview with a trained study staff member using a structured questionnaire in Yoruba was administered to gather information on socioeconomic status, prior education, obstetrics history, current health status, pertinent past medical history, and family history. The questionnaires were then back-translated and checked for accuracy. Participants also received routine antenatal care and blood draws for complete blood count, serum biomarker levels, and malaria parasites once during their second and third trimesters, as well as spirometry tests. All women underwent ultrasound scans at least six times during pregnancy