

Lifestyle and pregnancy loss in a contemporary cohort of women recruited before conception: The LIFE Study

05 Germaine M. Buck Louis, Ph.D., M.S.,^a Katherine J. Sapa, M.Phil., M.P.H.,^a
 14 Enrique F. Schisterman, Ph.D., M.A.,^b Courtney D. Lynch, Ph.D., M.P.H.,^c José M. Maisog, M.D., M.S.,^d
 15 Katherine L. Grantz, M.D., M.S.,^b and Rajeshwari Sundaram, Ph.D., M.S.^e

^a Office of the Director and ^b Epidemiology Branch, Division of Intramural Population Health Research, *Eunice Kennedy Shriver National Institute of Child Health and Human Development*, Rockville, Maryland; ^c Department of Obstetrics and Gynecology, The Ohio State University College of Medicine, Columbus, Ohio; ^d Glotech, Inc.; and ^e Biostatistics and Bioinformatics Branch, Division of Intramural Population Health Research, *Eunice Kennedy Shriver National Institute of Child Health and Human Development*, Rockville, Maryland

Objective: To estimate pregnancy loss incidence in a contemporary cohort of couples whose lifestyles were measured during sensitive windows of reproduction to identify factors associated with pregnancy loss for the continual refinement of preconception guidance.

Design: Prospective cohort with preconception enrollment.

Setting: Sixteen counties in Michigan and Texas.

Patient(s): Three hundred forty-four couples with a singleton pregnancy followed daily through 7 postconception weeks of gestation.

01 **Intervention(s):** None. Couples daily recorded use of cigarettes, caffeinated and alcoholic beverages, and multivitamins. Women used
 29 fertility for ovulation detection and digital pregnancy tests. Pregnancy loss was denoted by conversion to a negative pregnancy test,
 30 onset of menses, or clinical confirmation depending upon gestation. Using proportional hazards regression and accounting for right
 31 censoring, we estimated adjusted hazard ratios and 95% confidence intervals (aHR, 95% CI) for couples' lifestyles (cigarette smoking,
 32 alcoholic and caffeinated drinks, multivitamins) during three sensitive windows: preconception, early pregnancy, and periconception.

Main Outcome Measure(s): Incidence and risk factors for pregnancy loss.

Result(s): Ninety-eight of 344 (28%) women with a singleton pregnancy experienced an observed pregnancy loss. In the preconception window, loss was associated with female age ≥ 35 years (1.96, 1.13–3.38) accounting for couples' ages, women's and men's consumption of >2 daily caffeinated beverages (1.74, 1.07–2.81; and 1.73, 1.10–2.72, respectively), and women's vitamin adherence (0.45, 0.25–0.80). The findings were similar for lifestyle during the early pregnancy and periconception windows.

Conclusion(s): Couples' preconception lifestyle factors were associated with pregnancy loss, although women's multivitamin adherence dramatically reduced risk. The findings support continual refinement and implementation of preconception guidance. (Fertil Steril® 2016; ■: ■–■. ©2016 by American Society for Reproductive Medicine.)

Key Words: Caffeine, lifestyle, miscarriage, pregnancy loss, multivitamins

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Reprint requests: Germaine M. Buck Louis, Ph.D., M.S., Office of the Director, Division of Intramural Population Health Research, *Eunice Kennedy Shriver National Institute of Child Health and Human Development*, 6100 Executive Boulevard, Room 7B03, Rockville, Maryland 20852 (E-mail: louisg@mail.nih.gov).

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Over the past few decades, the detection of pregnancy for many women not receiving infertility treatment has shifted from clinical settings to the privacy of the home. This change is largely attributed to the development of a hCG beta-subunit radioimmunoassay (1), leading to the availability of the first early pregnancy test in 1976. Currently, there are ≈ 60 home pregnancy test kits available in the United States,

accounting for approximately \$228 million in annual sales (2, 3). Home pregnancy tests now generate more revenue than any other over-the-counter home diagnostic test, including those for blood pressure or glucose testing (4), and are used by approximately 85%–90% of women for identifying pregnancy (5).

The shift in pregnancy detection from the clinical setting to the home means that women may now recognize more pregnancies than they did when clinical identification was the norm, usually occurring after one or two missed periods. To date, only a few prospective cohort studies with preconception enrollment of women or couples have ever been conducted worldwide to estimate the incidence of pregnancy loss. Overall, loss rates range from a low of 8% among 92 pregnant women in Newcastle, United Kingdom (6), to a high of 52% among 118 pregnant women in Southampton, United Kingdom (7). Recent data from the U.S. National Survey of Family Growth noted an increasing pattern of self-reported miscarriage between 1970 and 2000, with much of the increase being for losses in the first 7 weeks of gestation, possibly reflecting women's use of home pregnancy testing (8). While various risk factors have been identified from past research ranging from health and pregnancy history to lifestyle, recent guidance from the American College of Obstetricians and Gynecologists notes the absence of any known interventions to prevent pregnancy loss except for anti-phospholipid syndrome and P supplementation for recurrent losses (9).

Another notable societal change in pregnancy is the shift in thinking from pregnant females to pregnant couples, as evident by colloquial terms such as “we are pregnant” along with the early and sustained involvement of male partners during prenatal care and delivery in many cases. Despite such changes, research has traditionally focused on characteristics of either the female or male partner relative to pregnancy loss but not both in light of few couples-based cohorts.

We sought to estimate the incidence of pregnancy loss and lifestyle risk factors in a contemporary cohort of couples desiring pregnancy who were recruited before conception and followed throughout trying to conceive and pregnancy. This design facilitated the capture of early pregnancy and losses consistent with the time period in which most losses occur. Pregnancy loss is an endpoint indicative of reproductive and/or developmental toxicity that may be associated with a variety of environmental exposures. Another unique aspect of this design is the ability to assess potential male-mediated risk factors for pregnancy loss such as age, employment, and use of cigarettes, alcohol, and caffeine in the context of women's lifestyle (10–13). As such, this approach goes beyond most of the available research conducted to date that focuses exclusively on female determinants and offers insight for preconception guidance that is increasingly focusing on both men and women.

MATERIAL AND METHODS

Study Design and Population

The study cohort comprised 347/501 (69%) women who had an observed pregnancy while participating in the LIFE Study, which was designed and powered to examine the association

between environmental and lifestyle factors and fecundity impairment among couples, including pregnancy loss. We excluded three couples with twin pregnancies, resulting in a cohort comprising 344 couples with singleton pregnancies. The LIFE Study used population-based sampling frameworks to recruit couples discontinuing contraception for purposes of becoming pregnant from 16 counties in Michigan and Texas. By design, eligibility criteria were minimal and included [1] being in a committed relationship; [2] ability to communicate in English or Spanish; [3] women ages 18–40 and men ages ≥ 18 years; [4] women's menstrual cycles between 21 and 42 days as required by the fertility monitors; [5] no history of injectable hormonal contraception in the past year or currently breastfeeding for 6+ months; [6] no clinically diagnosed infertility in either partner; and [7] off contraception < 2 months. Before enrollment, female partners' urine was tested to ensure they were not pregnant. Human subjects approval was obtained from participating institutions, and all men and women gave written informed consent before data collection. Complete details about the population-based sampling framework used along with response rates have been published elsewhere (14).

Data Collection and Follow-up

Couples were interviewed individually upon enrollment to ascertain sociodemographic, lifestyle, and medical history information, followed by the measurement of height and weight to calculate body mass index (BMI). The couple was then instructed in the completion of daily journals to record their lifestyle behaviors in a manner consistent with how people think about such exposures (e.g., number of cigarettes smoked per day, number of alcoholic and caffeinated beverages consumed per day, taking daily multivitamins). Females also reported sexual intercourse, menses, and home pregnancy test results. Couples completed journals daily until a positive home pregnancy test or up to 12 months of trying. Pregnant women continued journals daily through 7 postconception weeks of gestation and then monthly journals until a loss or delivery. Journal entries were purposefully designed to be short to minimize participant burden and encourage daily adherence.

Standardized prompts were provided in the daily journals regarding lifestyle. Specifically, one alcoholic drink equaled one can or bottle of beer, a glass of wine, a shot of liquor, or a mixed drink. A caffeinated drink equaled a cup of coffee or tea or a can of soda (excluding decaffeinated or caffeine-free beverages). Vitamins included over-the-counter multivitamins and prescription prenatal vitamins and were dichotomized relative to daily usage (yes/no). Couples reported the daily number of cigarettes smoked and alcoholic and/or caffeinated beverages consumed and were instructed to record a zero if none was used. Couples had the option of reporting data via the web or of returning weekly journal cards consistent with prospective measurement.

Home Fertility and Pregnancy Testing

Women were trained in the use of the Clearblue fertility monitor (Inverness Medical Innovations), a urinary test kit

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