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Maternal race/ethnicity as a risk factor for cervical insufficiency

 Lisette D. Tanner^{a,*}, Lue-Yen Tucker^b, Debbie Postlethwaite^b, Mara Greenberg^a
^a Department of Obstetrics and Gynecology, Kaiser Permanente Oakland Medical Center, Oakland, CA, USA^b Division of Research, Kaiser Permanente Northern California, Oakland, CA, USA

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ABSTRACT

Background: Preterm birth (PTB) affects 1 in 9 pregnancies in the United States. There are well known but poorly understood racial/ethnic disparities in PTB rates. The role that racial/ethnic disparities in cervical insufficiency (CI) may play in the overall disparities in preterm birth rates is unknown.

Objective: The primary objective of this study was to examine racial/ethnic differences in risk of CI.

Study design: We conducted a retrospective cohort study of singleton pregnant women in 2012 who were members of Kaiser Permanente Northern California (KPNC), excluding elective termination, delivery outside KPNC, and loss to follow-up. The primary outcome was CI; the secondary outcomes included stillbirth, PTB, and neonatal intensive care unit (NICU) admission. We compared rates of these outcomes among women of different racial/ethnic background. Multivariable logistic regression modeling was used to assess other potential risk factors for CI, including maternal age, parity, medical co-morbidities, prior cervical procedures, prior pregnancy terminations, and history of PTB.

Results: A total of 34,173 women who were pregnant in 2012 were included in the study. The racial/ethnic makeup of the cohort was 38.6% White, 25.8% Asian, 25.1% Hispanic, 7% Black, and 3.5% other. Approximately 1% (401) of women were diagnosed with CI. Black women had a significantly higher rate of CI (3.2%) compared to White women (0.9%, $P < 0.001$) as well as higher rates of PTB (9.2%). Infants born to black women had higher rates of NICU care (8.7%) compared to other racial/ethnic groups. Regression analysis showed that Black race/ethnicity was significantly associated with CI compared to Whites (OR 2.89, 95% CI 2.13–3.92) after controlling for other variables associated with CI.

Conclusion: Black women had higher odds of CI compared to White women. This disparity may contribute to the significantly higher rate of PTB among Black women nationally. Further investigation of this association may provide important contributions to our understanding of both CI and PTB.

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Introduction

Cervical Insufficiency (CI) is a condition in which the cervix painlessly dilates and shortens, which can result in preterm delivery and/or pregnancy loss. The pathophysiology of this condition is not completely understood. Many theories have been presented to explain and predict which women will be affected. One such theory suggests that some women exhibit natural biologic variation in cervical collagen, cervical elastin, and other structural components of cervical connective tissue that resist softening, effacement, and dilation [1]. Other theories suggest that inflammation and subclinical changes in the normal microbiome of the vagina may contribute to changes in the structural integrity of

the cervix [2]. An incomplete understanding of the causes of this condition has limited the development of effective treatments and reduction in resultant preterm birth (PTB).

PTB is the leading cause of neonatal morbidity and mortality in the US [3]. According to the Centers for Disease Control and Prevention, PTB affects 1 in 9 infant deliveries and costs approximately \$26 billion each year in total healthcare costs [3]. The US was reported to have a 12–13% PTB rate as compared to 5–9% in Europe [4]. Disparities in PTB between various racial/ethnic groups are well established. In particular, infants born to non-Hispanic Black mothers are more than 1.5 times as likely to be born premature compared to non-Hispanic White mothers [4]. There is an even more pronounced disparity in preterm birth with Black mothers having a 3- to 6-fold increased relative risk of preterm birth compared with white mothers [5]. It has been difficult to pinpoint why these differences exist, likely given multiple potential causal pathways. Also while the overall disparity in PTB is well known, disparities in preterm labor versus CI has not been studied discretely. Specifically, the role that a

* Corresponding author at: Department of Obstetrics, Gynecology, and Reproductive Sciences, McGovern medical school at the University of Texas Health Science Center at Houston, 6431 Fannin St., Houston, TX 77030, USA.

E-mail address: Lisette.D.Tanner@uth.tmc.edu (L.D. Tanner).

possible racial/ethnic disparity in CI may play in the overall PTB disparity, especially among Black women, has not been fully elucidated. To date, only one study has investigated a potential racial/ethnic disparity in CI. That study was based on birth certificate data with maternal self-report of CI [6]. A better understanding of how maternal demographics impact our patients can help us further develop screening and preventive tools to improve care and potentially contribute to reduction in PTB rates with associated decreases in overall health care costs. We therefore seek to examine the impact of race/ethnicity as an independent risk factor for CI. The primary aim of the study was to determine and compare the proportion of women in each racial/ethnic subgroup with a diagnosis of CI. Secondary aims were decided a priori to be rates of PTB and NICU admission among different race/ethnicities. Our primary hypothesis is that race/ethnicity is an independent risk factor for CI.

Materials and methods

We performed a retrospective cohort study using medical records for all eligible women in the Kaiser Permanente Northern California region. At Kaiser Permanente Northern California (KPNC), we have a large volume of deliveries, of over 30,000 births per year, from multiple medical centers, among a diverse patient population, supported by a robust electronic medical record (EMR) system. This allows for a unique opportunity, likely available only within a large integrated health care delivery system, to study rare outcomes such as CI, and the association with maternal race/ethnicity. The study was conducted using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code for CI, ICD-9-CM procedure codes, and/or Current Procedural Terminology (CPT) codes associated with procedures for treatment of CI (Appendix A). Demographic, medical, and obstetric data of interest were abstracted from the comprehensive EMR system within KPNC. Women were considered eligible for inclusion in the study if they had a pregnancy episode that started anytime between January 1, 2012 and December 31, 2012, continuous KPNC membership as well as

delivery within the KPNC system. We excluded women who had multiple gestations, abortions (whether spontaneous or elective), delivered outside KPNC, or were lost to follow up.

Self-reported maternal racial/ethnic background (Hispanic, non-Hispanic White, non-Hispanic Black, Asian including Pacific Islander, other) for women within the patient sample was collected. Other data elements of interest collected included maternal age at delivery, self-reported income and education level, number of prior pregnancies, number of prior pregnancy terminations, history of prior preterm delivery, prior cervical procedures (defined as any prior loop electrosurgical excision procedure or cold knife cone), medical conditions (e.g. diabetes, hypertension, renal disease, antiphospholipid antibody syndrome [APLS], hemoglobinopathy, herpes simplex virus, anemia, autoimmune disorders [systemic lupus erythematosus, rheumatoid arthritis, scleroderma, Sjogren's syndrome, and mixed connective tissue disorder], etc.). Information collected on neonates of the mothers with CI included gestational age at delivery, which was used to determine diagnosis of PTB, evidence of admission to the Neonatal Intensive Care Unit (NICU), diagnosis of Acute Respiratory Distress Syndrome, and fetal/neonatal death. Maternal race/ethnicity and other demographic data were classified based upon patient report on hospital intake forms.

Structured review of EMR was performed on a random sample of 700 (2%) of women to validate electronic data abstraction method by correlating ICD-9 code for CI with patient's clinical presentation and context of diagnosis, to ensure that the CI diagnosis was in fact accurate. The targeted review revealed 95% accuracy with an estimated margin of error of 0.025 (95% CI 93.2–96.6%) on all data elements except number of prior pregnancies (81%) and pregnancy terminations (87%).

Prior to the start of the study, to determine an accurate sample size of study subjects to include, a preliminary data pull was performed that found approximately 33,700 women who gave birth in 2010. Roughly 2% of those pregnancies were multiple gestations. We estimated 8% of these women were non-Hispanic Black (hereafter termed Black) and 40% were non-Hispanic White (hereafter termed White). The proportions of these 2 racial/ethnic

Table 1
Demographic and Clinical Characteristics by Maternal Racial/Ethnic Subgroups.

Characteristics	White 13,200 (38.6)	Black 2395 (7.0)	Hispanic 8565 (25.1)	Asian 8808 (25.8)	Other 1205 (3.5)	P
Age at Delivery (years), Median [IQR]	31 [27–34]	28 [23–33]	29 [24–33]	32 [29–35]	32 [28–35]	<0.001
Age Group (years)						<0.001
<18	66 (0.5)	52 (2.2)	195 (2.3)	19 (0.2)	5 (0.4)	
18–34	9997 (75.7)	1927 (80.5)	6759 (78.9)	6245 (70.9)	848 (70.4)	
≥35	3137 (23.8)	416 (17.4)	1611 (18.8)	2544 (28.9)	352 (29.2)	
Education Level						<0.001
Less than high school	158 (1.2)	100 (4.2)	702 (8.2)	140 (1.6)	30 (2.5)	
High school or GED	3419 (25.9)	1058 (44.1)	3465 (40.5)	1660 (18.9)	334 (27.7)	
College degree or higher	4916 (37.2)	412 (17.2)	1423 (16.6)	4251 (48.3)	447 (37.1)	
Unknown	4707 (35.7)	825 (34.5)	2975 (34.7)	2757 (31.2)	394 (32.7)	
Parity						<0.01
0	6302 (47.7)	1042 (43.5)	3431 (40.1)	4112 (46.7)	504 (41.8)	
1	4659 (35.3)	762 (31.8)	2769 (32.3)	3264 (37.1)	424 (35.2)	
≥2	2239 (17.0)	591 (24.7)	2365 (27.6)	1432 (16.3)	277 (23.0)	
Prior Pregnancy Termination						<0.01
0	8182 (62.0)	1078 (45.0)	5199 (60.6)	5641 (64.0)	670 (55.7)	
1	3054 (23.1)	623 (26.0)	2112 (24.7)	2054 (23.3)	310 (25.7)	
≥2	1964 (14.9)	694 (29.0)	1254 (14.7)	1113 (12.7)	225 (18.6)	
Prior Preterm Birth	596 (4.6)	191 (8.0)	541 (6.3)	407 (4.6)	68 (5.6)	<0.001
Prior Cervical Procedure	75 (0.6)	68 (2.8)	76 (0.9)	57 (0.7)	9 (0.7)	<0.001
Diabetes	75 (0.6)	23 (1.0)	99 (0.7)	62 (0.7)	9 (0.8)	0.04
Hypertension	958 (7.3)	238 (9.9)	459 (5.4)	465 (5.3)	74 (6.1)	0.99
Renal Disease	182 (1.4)	51 (2.1)	142 (1.7)	90 (1.0)	15 (1.2)	<0.01
Antiphospholipid Antibody Syndrome	67 (0.5)	9 (0.4)	17 (0.2)	16 (0.2)	3 (0.3)	<0.001
Autoimmune Disorders	73 (0.6)	11 (0.5)	54 (0.6)	45 (0.6)	3 (0.3)	0.46

Data presented as n (%) unless otherwise indicated. Overall comparisons across racial/ethnic subgroups tested using Chi-square for categorical variables and Kruskal-Wallis for age.

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