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Ultrasound-Confirmed, Age-Specific Uterine Leiomyoma Incidence in a Cohort of Black Individuals

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Original Research

Ultrasound-Confirmed, Age-Specific Uterine Leiomyoma Incidence in a Cohort of Black Individuals

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OBJECTIVE: To estimate the age-specific incidence of uterine leiomyomas identified by transvaginal ultrasonography among participants in SELF (Study of Environment, Lifestyle & Fibroids).

METHODS: SELF is a longitudinal cohort study of individuals aged 23–35 years who self-identified as Black. Participants were recruited from the Detroit, Michigan, area and underwent up to five transvaginal ultrasonograms over a period of up to 10 years to identify uterine leiomyomas. We randomly imputed incidence dates between the last ultrasonogram date in which no leiomyomas were detected and the date of the ultrasonogram in which leiomyomas were first detected. We used Poisson regression to estimate age-specific incidence rates per 1,000 person-years with 95% CIs. The rates were then compared with those of the BWHS (Black Women's Health Study) and the NHS II (Nurses' Health Study II)—two prospective cohort studies based on self-reported leiomyoma diagnoses.

RESULTS: In this cohort, 1,693 participants completed a baseline interview and ultrasonogram. We excluded 385 (22.7%) participants with leiomyomas detected during baseline, seven participants whose ultrasonograms were poor quality, and 60 participants with only a baseline ultrasonogram. Among the remaining 1,241 participants, the overall incidence rate was 53.9 cases per 1,000 person-years (95% CI 48.6–59.6). The age-specific incidence rates (cases/1,000 person-years) were: younger than 30 years: 49.7, 95% CI 40.9–59.9; 30–34 years: 55.2, 95% CI 47.0–64.3; and 35–39 years: 58.2, 95% CI 47.3–70.9. Among participants aged younger than 30 years, the incidence rate in SELF was more than double that of the BWHS or the NHS II.

CONCLUSION: The high age-specific leiomyoma incidence rates in this prospective ultrasound-based study indicate that many young Black individuals with leiomyomas go undiagnosed. These data suggest that individuals could benefit from ultrasound screening when they experience symptoms compatible with leiomyomas (eg, heavy menstrual bleeding, anemia, pelvic pain).

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Uterine leiomyomas, commonly known as leiomyomas, are benign neoplasms that can cause heavy menstrual bleeding, pelvic pain, bulk symptoms and infertility and are a leading cause of hysterectomy in the United States.[1] However, there are no effective pri-

mary prevention strategies for leiomyomas.[1] Black individuals are younger at diagnosis compared with White individuals and they tend to have more and larger leiomyomas when first diagnosed.[2] Ultrasonography is the most widely-used clinical technique for identifying leiomyomas,[3] but imaging is largely only performed during pregnancy, when symptoms are present and reported to a physician or nurse, or in follow-up to abnormal bimanual examination findings. In a study with ultrasound screening for leiomyomas in individuals aged 35–49 year, approximately 50% of individuals with leiomyomas reported no prior diagnosis, though some had symptoms.[4] This variation in diagnosis and symptom presentation, along with the need for imaging to confirm leiomyomas, has led to the misclassification of noncases and an underestimation of true leiomyoma incidence, which is needed to understand the effect of disease on population health. If it is appreciated that leiomyomas often develop at young ages, individuals could have earlier intervention with minimally invasive treatments that could delay or eliminate the need for interventions such as hysterectomy.

Two large prospective epidemiologic cohort studies, the NHS II (Nurses' Health Study II)[5] and the BWHS (Black Women's Health Study),[6] estimated age-specific leiomyoma incidence rates. Both studies defined leiomyomas based on self-reported clinical diagnoses, documenting that self-reported leiomyoma incidence rates for Black individuals at hysterectomy were a fraction of the leiomyoma incidence rates estimated by hysterectomy or clinically indicated ultrasonogram. These results demonstrate the challenge of calculating age-specific incidence rates when the entire population is not screened with imaging.

The purpose of the present study was to estimate the age-specific leiomyoma incidence rates for up to 10 years of follow-up in the first longitudinal study with repeated transvaginal ultrasound screenings of a closed cohort of participants: SELF (Study of Environment, Lifestyle & Fibroids). Participants self-identified as Black and were aged 23–35 years at time of enrollment (2010–2012). Participants were screened with ultrasonography for the detection of leiomyomas at baseline and at four follow-up visits during 2010–2021. To understand how screening with ultrasonography compared with self-reported age at diagnosis may affect incidence rates, we compared the age-specific uterine leiomyoma incidence rates from SELF with those rates previously reported in the NHS II[5] and BWHS.[6]

METHODS

SELF is an ongoing longitudinal cohort study specifically designed to study incidence and growth of uterine leiomyomas with standardized ultrasound assessments.[7,8] Briefly, in 2010–2012, we enrolled 1,693 individuals who self-identified as Black or African American, were aged 23–35 years, had a uterus and did not report a prior diagnosis of uterine leiomyomas. We have previously published details of participant recruitment; briefly, we mailed letters to Henry Ford Health patients who were aged 23–34 years to invite study participation and patients 35–65 to ask them to share study information with those who may be eligible. Media advertisements and information booths at community events were also used to recruit possible participants. Participants were provided stipends for research activities. We did not collect data on sex assigned at birth or gender identity. Participants signed written informed consent for all research activities approved by the IRBs at Henry Ford Health, the National Institute of Environmental Health Sciences, and Boston University Medical Campus. Participants completed baseline visits and were asked to return at intervals to complete four follow-up clinic visits at Henry Ford Health clinic locations in Detroit (median time between baseline and first follow-up visit: 1.6 years; median time between follow-up visit 1 and follow-up visit 2: 1.6 years; median time between follow-up visit 2 and follow-up visit 3: 1.6 years; and median time between follow-up visit 3 and follow-up visit 4: 2.6 years).

At each study-specific clinic visit (baseline and four follow-up visits), participants completed self-administered questionnaires and telephone interviews about their behaviors and health history, including any uterine surgeries in which uterine leiomyomas could be detected or treated, such as hysterectomy and myomectomy. The ultrasound team performed a transvaginal ultrasonography, and participants provided blood and urine specimens and vaginal swabs and had their height and weight measured. Some participants were pregnant at the time of a scheduled study visit (less than 4% in each follow-up); study visits were delayed for these participants until 3–6 months postpartum, when postpartum uterine changes would not interfere with ultrasound imaging.

In this cohort, 1,693 participants enrolled in the study and had a baseline interview and ultrasonogram. The 385 (22.7%) participants who had a leiomyoma detected during the baseline ultrasonogram were excluded from these analyses of incident leiomyomas; their age distribution is presented in Appendix 1, available online at http://links.lww.com/AOG/C923. We further excluded seven participants whose ultrasonograms were of poor quality and 60 participants who had only a baseline ultrasonogram

and no additional ultrasonograms. We analyzed incidence in the remaining 1,241 participants (Fig. 1).

The details of the ultrasound procedures have been described previously.[7,8] Henry Ford Health clinical staff performed all ultrasonograms transvaginally unless an additional abdominal ultrasonogram was needed for a complete assessment.[8] A fixed cadre of experienced ultrasonographers (3 or more years of experience in gynecologic ultrasound) was trained to ensure high data quality. Study-specific training included an emphasis on distinguishing leiomyomas from other pathologic changes in the uterus (eg, polyps).

We did not schedule ultrasonograms to correspond with any phase of the menstrual cycle, and we asked participants to empty their bladders before imaging. We used a standardized data-collection form and asked ultrasonographers to map and number all leiomyomas on a diagram. Ultrasonographers identified each leiomyoma 0.5 cm or larger in diameter and characterized the six largest leiomyomas in terms of size and location. The ultrasonographers placed the ultrasound calipers from outer border to outer border to assess each diameter, which were measured in three perpendicular planes (longitudinal, anterior-posterior, transverse), and the ultrasonographer repeated three separate passes through the uterus. They recorded any leiomyoma-like echo pattern that could not be visualized in all three planes as a "questionable fibroid" (referred to in the remainder of this article as "questionable leiomyoma"). Additional imaging was not performed.[9,10]

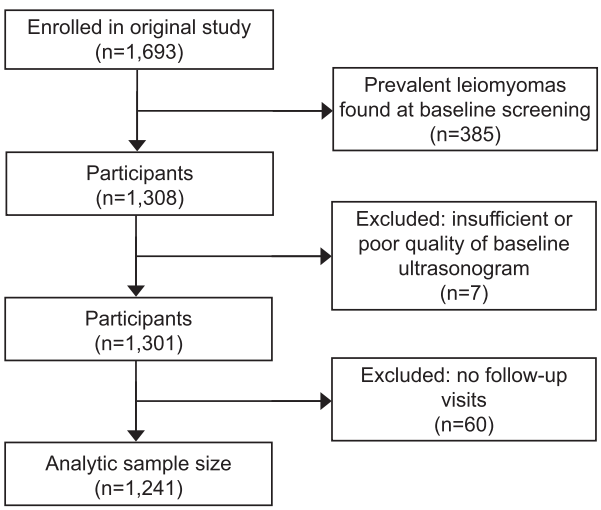

Fig. 1. Study participant flowchart.

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Together, each study ultrasonographer and the lead ultrasonographer (T.C.) reviewed the first 10 ultrasound examinations performed by each of the study ultrasonographers. The lead ultrasonographer provided feedback to the ultrasonographers at that time and throughout the baseline visit and three follow-up visits as the lead ultrasonographer reviewed 8% of all ultrasonograms performed by each ultrasonographer each month, with overrepresentation of ultrasonograms showing leiomyomas. We did not record the agreement of each review (eg, agreement, recommended revision). The lead ultrasonographer reviewed all questionable leiomyomas. After this additional review, there were three participants with a questionable leiomyoma that were considered incident leiomyoma cases.

For participants reporting any treatment of their uterus during the study, we requested procedure details and medical records from the facility where they received the treatment. We reviewed the medical records for the presence of leiomyomas, including procedure notes and any pathology reports, and recorded the date of the procedure. For the one participant who had not attended all follow-up visits and had a leiomyoma first identified by medical records rather than on ultrasonogram, we considered the date of surgery to be the date of first leiomyoma detection.

We calculated person-years at risk from the start of follow-up (2010–2012) until the ultrasound detection of incident leiomyomas or a censoring event (ie, hysterectomy without leiomyomas or loss to follow-up), whichever came first. Because leiomyomas were observed at irregular intervals (study visits), a random date imputation method was used rather than midpoint imputation, which has been shown to create biased estimates when participants begin to miss study visits, which is expected in a longitudinal cohort study.[11] We randomly imputed incidence dates between the last ultrasonogram date in which no leiomyomas were detected and the date of the ultrasonogram in which leiomyomas were first detected. Person time was right-censored at either the date of the last ultrasonogram (if leiomyomas were not present) or the imputed date of leiomyoma detection. We then calculated age-specific incidence rates, per 1,000 person-years, as the number of participants with incident leiomyomas detected divided by the total person-time at risk in each age category (younger than 30, 30–34, 35–39 years). We used Poisson regression to estimate age-group-specific incidence rates and 95% CIs. Given the enrollment ages, few participants reached age 44 year by the end of follow-up, and only

188 person-years were accrued during person-ages 40–44 years. Therefore, we do not present the incidence rate for this age group.

We compared the age-specific incidence rates in SELF to those reported in NHS II and BWHS, both of which relied on self-reported clinical diagnosis. The NHS II used data from 1,309 premenopausal Black women with intact uteri to estimate age-specific leiomyoma incidence during a 4-year period in which 140 incident cases were reported and confirmed.[5] The BWHS is a prospective cohort study that examined incidence rates for self-reported leiomyoma diagnoses over a period of 4 years (1997–2001) among women who identified as Black or African American, were premenopausal, had intact uteri, and were aged 23–69 years at the start of follow-up.[6] In the BWHS, there were 76,711 woman-years of follow-up and 2,637 incident cases of leiomyomas reported by 22,895 participants.

RESULTS

At enrollment, the distribution of the participants was fairly evenly distributed across the age intervals (Table 1). A quarter of the participants had earned at least a college degree, and most other participants had at least some college education. Almost half of the participants had a total household income that was less than $20,000. Twenty-one percent of the participants had body mass indexes (BMIs, calculated as weight in kilograms divided by height in meters squared) of 25–29, and 58.9% had BMIs of 30 or higher. Nearly three quarters of the participants had never smoked. Approximately one third (36.1%) of the participants were nulliparous, and 26.9% of those with at least one prior live birth breastfed their children for more than 6 months (cumulative across all of their children). Among the parous participants, approximately one quarter had delivered in the 2 years before enrollment. Almost two thirds of the participants reported menarche at age 11–13 years, with 17.3% of the participants reporting age at menarche at 10 years or younger. During the baseline interview, 11.7% of the participants were using oral contraceptives and 6.5% were using depot medroxyprogesterone acetate. The participants enrolled in SELF were aged 33–45 years at the time of their most recent follow-up visit.

The 1,241 participants eligible for incidence analyses contributed 7,038 person-years to the analyses. There were 379 incident cases of leiomyoma, of which 378 were identified through study ultrasonogram and one was identified through medical records; 371 of the 379 incident cases were in participants aged younger than 40 years (Appendix 2, available online at http://links.lww.com/AOG/C923). The overall incidence rate was 53.9 cases per 1,000 person-years (95% CI 48.6–59.6), or an average risk of 5.4% per year (95% CI 4.9–6.0). The age-specific incidence rates (cases/1,000 person-years) were: younger than 30 years: 49.7, 95% CI 40.9–59.9; 30–34 years: 55. 2, 95% CI 47.0–64.3; and 35–39 years: 58.2, 95% CI 47.3–70.9 (Table 2).

Figure 2 presents a comparison of incidence rates among the SELF, BWHS, and NHS II cohorts. In NHS II, overall, there were 140 cases confirmed by ultrasonogram or hysterectomy (30.6 cases/1,000 person-years, 95% CI 25.5–35.7). The age-specific incidence rates of self-reported cases diagnosed by ultrasonogram or hysterectomy per 1,000 person-years for Black or African American women (N=1,309) were: 26–29 years: 5.6; 30–34 years: 23.3; 35–39 years: 38.1; and 40–44 years: 34.5. In the BWHS, when the incident leiomyoma was confirmed by ultrasonogram or hysterectomy, the age-specific incidence rates (cases/1,000 person-years) were: younger than 30 years: 17.8, 95% CI 16.0–19.8; 30–34 years: 28.2, 95% CI 25.9–30.7; 35–39 years: 34.6, 95% CI 31.9–37.5; 40–44 years: 39.8, 95% CI 36.5–43.4; and 45–49 years: 35.8, 95% CI 31.6–40.5.[6] Among participants younger than age 30 years, the incidence rate in SELF was more than double that of either the BWHS or the NHS II.

DISCUSSION

In this prospective cohort study of premenopausal individuals who identify as Black or African American, the age-specific rates exceeded prior estimates reported in epidemiologic cohort studies that did not systematically screen all participants with ultrasonograms. For example, the overall age-standardized incidence rate was 30.6 per 1,000 person-years in NHS II, similar to the BWHS estimate of 34.4 (95% CI 33.1–35.7) cases per 1,000 person-years,[6] but less than the 53.9 (95% CI 48.6. 59.6) cases per 1,000 person-years in SELF. Prospective studies that directly query participants about clinical diagnoses of leiomyomas underestimate incidence rates. However, this underestimation based on self-report is less than underestimation of incidence in studies that use only medical record or claims data.[6]

The results from our prospective study of ultrasound imaging verify that leiomyoma incidence begins at a young age in Black individuals. This is consistent with prior reports using cross-sectional ultrasonogram data and statistical modelling to estimate age-specific cumulative incidence of leiomyomas. Those studies suggested that leiomyoma onset begins about a decade earlier for young Black

Table 1. Descriptive Information at the Baseline Clinic Visit Among 1,241 Reproductive-Aged Black Participants in SELF (Study Environment, Lifestyle & Fibroids)

Characteristic	n (%)
Sociodemographic variables	
Age (y)	
23–25	315 (25.4)
26–28	321 (25.9)
29–31	327 (26.3)
32–35	278 (22.4)
Education level (y)*	
High school graduate or equivalency certificate (12)	286 (23.1)
Some college (13–15)	638 (51.4)
Bachelor's degree or more (16 or more)	316 (25.5)
Annual household income ($)†	
Less than 20,000	568 (46.2)
20,000–50,000	474 (38.5)
Greater than 50,000	188 (15.3)
Anthropometric and lifestyle variables	
BMI (kg/m^2)	
Lower than 25	249 (20.1)
25–29	261 (21.0)
30–34	236 (19.0)
35–39	205 (16.5)
40 or higher	290 (23.4)
Cigarette smoking	
Never	908 (73.2)
Past	91 (7.3)
Current, less than 10 cigarettes/d	185 (14.9)
Current, 10 cigarettes/d or more	57 (4.6)
Reproductive variables	
Parity (births)	
Nulliparous	448 (36.1)
1	331 (26.7)
2	233 (18.8)
3 or more	229 (18.4)
Breastfeeding duration (mo)‡	
6 or less	580 (73.1)
More than 6	213 (26.9)
Time since last birth (y)‡	
Less than 2	209 (26.3)
2–4	271 (34.2)
5–9	229 (28.9)
10 or more	84 (10.6)
Age at menarche (y)	
10 or younger	215 (17.3)
11	255 (20.6)
12	343 (27.6)
13	203 (16.4)
14 or older	225 (18.1)
Current oral contraceptive use	
No	1,096 (88.3)
Yes	145 (11.7)
Current DMPA use	
No	1,160 (93.5)
Yes	81 (6.5)
Typical cycle length (d)§	
Less than 25	254 (20.7)
25–27	158 (12.9)
28–31	561 (45.7)
32 or more	98 (8.0)
Cycles too irregular to say	57 (4.6)
No period within past year	100 (8.1)

BMI, body mass index; DMPA, depot medroxyprogesterone acetate.
* Data missing for one participant.
† Data missing for 11 participants.
‡ Among parous individuals, lifetime cumulative.
§ Data missing for 13 participants.

individuals compared with White individuals.[12] The incidence rate of 50 cases per 1,000 person-years for SELF participants in their 20s translates to a cumulative incidence of 30% by age 30 years and aligns with the early onset that was suggested by the prior work. Such age-specific data to verify modelled estimates for White individuals and those of other racial and ethnic groups are not yet available.

The young age of onset means that Black individuals have more years for premenopausal hormones to drive leiomyoma growth compared with White individuals. Those with the highest risk of developing major symptoms are probably those with the earliest onset. Screening ultrasonograms at age 30 years for individuals with leiomyoma symptoms (heavy menstrual bleeding, anemia, pelvic pain), followed by growth-limiting treatments for those with leiomyomas, could substantially reduce their high health burden from leiomyomas.

The results from our study also highlight the challenges of using data without widespread ultrasound screening to confirm leiomyoma status. In their study of medical record data and diagnoses codes from Kaiser Permanente in Washington, Yu et al[13] reported incidence rates for leiomyoma diagnoses were highest for the age group 45–49 years in 2014 with 24.0 cases per 1,000 person-years. They also reported that annual overall incidence rates (cases/1,000 person-years) declined over time from 13.9 in 2005 to 10.14 in 2014. The overall incidence rates are substantially lower than those reported in SELF (53.9 cases/1,000 person-years). The large difference in incidence rates between SELF and claims data suggest that claims data may better support studies of

Table 2. Age-Specific Incidence Rates Among 1,241 Reproductive-Aged Black Participants in SELF (Study of Environment, Lifestyle & Fibroids) Using Random Date Imputation

Age (y)	Person-Years of Follow-up	No. of Incident Leiomyomas	Age-Specific IR (95% CI)*
Younger than 30	2,212	110	49.7 (40.9–59.9)
30–34	2,937	162	55.2 (47.0–64.3)
35–39	1,701	99	58.2 (47.3–70.9)

IR, incidence rate.
* Defined as number of new cases per 1,000 person-years.

treatment frequency or relative treatment effectiveness rather than overall disease incidence. Furthermore, these differences between incidence rates defined by ultrasonogram and claims data suggest a need to better understand the way that individuals experience their leiomyomas and their treatment seeking behaviors, especially factors that could affect their ability to access care. It is critical to understand who receives a diagnosis and treatment and how they differ from those who are not diagnosed or treated.

The limitations of this work include the length of time between ultrasonograms, which averaged 2 years. Because an incident leiomyoma might have been detectable after only a few months, a shorter time interval likely would have resulted in slightly increased incidence estimates. However, the cost of conducting more ultrasonograms within shorter intervals would have made the cost of the study prohibitive and increased participant burden. The participants in SELF are also all from one area of the country (southeast Michigan), which may limit generalizability to other Black individuals if leiomyoma risk is associated with geographically specific environmental risk factors.

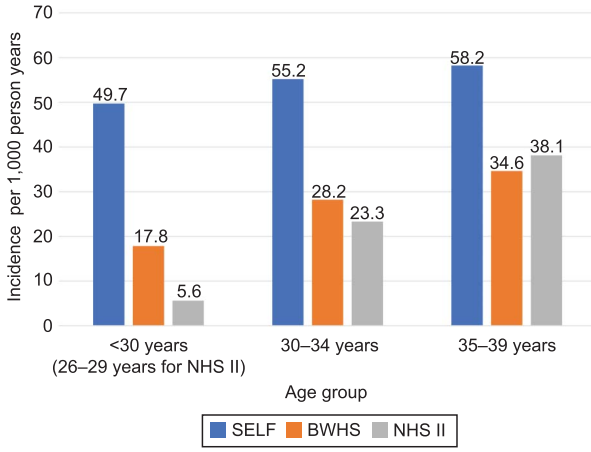

Fig. 2. Incidence rate of leiomyoma cases identified by ultrasonography or hysterectomy per 1,000 person-years. SELF (Study of Environment, Lifestyle and Fibroids) is the only study that screened all participants for leiomyomas with ultrasonography. BWHS, Black Women's Health Study; NHS II, Nurses' Health Study II.

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The prospective design and leiomyoma screening by ultrasonogram are unique and key strengths of this work, thereby allowing us to document a greater frequency of uterine leiomyomas in young Black individuals when compared with prior cohort studies. Thus, ultrasound studies are useful for advancing our knowledge about the true incidence and etiology of leiomyomas. The high retention rate of this study (greater than 80% over 10 years) is another strength.

In conclusion, this work highlights leiomyomas are a commonly detected neoplasm in Black individuals of reproductive age. Furthermore, our results, in comparison with prior epidemiologic studies, demonstrate the importance of imaging to identify both leiomyomas requiring surgical intervention as well as those for which individuals have not yet received a diagnosis. Knowledge of leiomyoma incidence rates can improve scientific understanding of the true prevalence of disease. The results from this study of Black individuals can also raise awareness of the elevated risk for young individuals who may benefit from ultrasound assessment when symptoms (heavy menstrual bleeding, anemia, pelvic pain) are compatible with leiomyomas as part of their clinical care. With continued follow-up of the SELF cohort, we will further assess leiomyomas in terms of their characteristics (growth, size, number, location), symptom burden, and their effect on quality of life.

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