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Uterine Leiomyomata and Cesarean Birth Risk: A Prospective Cohort with Standardized Imaging

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Abstract

Purpose—To determine if women with leiomyomata detected using uniform ultrasound methods are at increased risk of cesarean birth, without regard to indication.

Methods—Women were enrolled in *Right from the Start* (2000–2010), a prospective pregnancy cohort. Leiomyomata were counted, categorized, and measured during first trimester ultrasounds. Women provided information about demographics and reproductive history during first trimester interviews. Route of delivery was extracted from medical records or vital records, if the former were unavailable. Generalized estimating equations were used to calculate risk ratios (RRs) and 95% confidence intervals (CIs) for the risk of cesarean birth by leiomyoma presence and characteristics.

Results—Among 2,635 women, the prevalences of leiomyomata and cesarean birth were 11.2% and 29.8%, respectively. Women with leiomyomata, compared to those without, had a 27% increase in cesarean risk (RR 1.27, CI [1.17, 1.37]). The association was weaker following adjustment for maternal body mass index and age (adjusted RR (ARR) 1.11, CI [1.02, 1.20]). The adjusted risk was elevated for women with a single leiomyoma ≥ 3 centimeters in diameter (ARR 1.22, CI [1.14, 1.32]) and women with the largest total leiomyoma volumes (ARR 1.59, CI [1.44, 1.76]).

Conclusions—Women with leiomyomata were at increased risk for cesarean birth particularly, those with larger tumor volumes.

Keywords

Leiomyoma; cesarean section; epidemiology; prospective studies

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INTRODUCTION

During pregnancy, approximately 11% of women have leiomyomata detectable via ultrasound [1]. Black women are disproportionately affected, with a prevalence of 18%, compared to 8% in White women [1]. Estimates of prevalence and risks of pregnancy outcomes vary across studies due to differences in criteria used to define leiomyomata and underlying population characteristics.[2-7] Presence of leiomyomata has been associated with increased risk of cesarean birth [2-7].

Studies retrospectively identifying women with leiomyomata via routine clinical ultrasounds report adjusted odds ratios (AOR) for cesarean birth ranging from 1.2 to 2.1 [3-5]. Those relying on hospital birth records (i.e., billing codes) to identify these women suggest a sixfold increase in cesarean risk [6,7]. Many studies are biased to detect large or clinically concerning leiomyomata by ascertaining the presence of leiomyomata with medical record coding or at the time of cesarean, potentially inflating effect estimates. Inclusion criteria and adjustment for potential confounders also differ between studies, making comparisons of risk estimates difficult.

Leiomyoma presence may influence route of birth via complications that occur before onset of labor (placenta previa, malpresentation) or after the onset of labor (dysfunctional labor, obstruction). Each of these indications has been hypothesized to be in the causal pathway between leiomyomata and cesarean birth. However, the research question of most direct relevance to clinical care is: Are leiomyomata, associated with an overall increased risk of cesarean birth? This is of special interest as average maternal age rises and clinicians speculate about the contribution of increasing age and greater likelihood of leiomyomas as a potential contributor to the rising use of cesarean. Currently, leiomyomata during pregnancy are monitored by “expectant management;” there are no practice recommendations for selecting route of delivery due to their presence.

Clinical instinct produces both the view that leiomyomata are deleterious during pregnancy and a need to parse out any causal pathways leading to cesarean birth. However, risks for cesarean indicators due to leiomyomata presence are generally small and do not suggest intervening action; once placenta previa or breech presentation occurs, management options for leiomyomata are fixed. Treatment or removal of leiomyomata is actionable between pregnancies. Therefore, in general populations of women planning pregnancies, the magnitude of the overall risk of cesarean birth is most informative (inclusive of risk due to complications and patient/clinician preferences). The overall risk is currently the best estimate of the projected maximal reduction of cesarean risk that could be achieved by intervening on leiomyomata. An analysis that excludes or adjusts for casually related indications, such as breech presentation, will under-estimate the net effect of leiomyomata. Therefore, to address biases in prior studies and to understand the overall influence of leiomyomata on cesarean risk, we sought to determine if leiomyomata increase risk of cesarean birth, without regard to indication, among women with leiomyomata detected using uniform research ultrasound imaging methods in a prospective community-based pregnancy cohort.

METHODS

Study Population

Right from the Start (RFTS) is a community-recruited, prospective cohort study [8]. Between 2000-2011, the study enrolled women from locations in Texas, Tennessee, and North Carolina who were newly pregnant or trying to become pregnant. To be eligible for

the study, women were at least 18 years old, less than 13 weeks pregnant, spoke English or Spanish, planned to carry to term, and did not use assisted reproductive technologies [8].

Women whose information contributed to this analysis were enrolled between December 2000 and June 2010. Women may enroll more than once in RFTS, but only information from the first study pregnancy for each woman was used. During this time, there were 3,196 different women who had pregnancies resulting in a live birth after 20 weeks of gestation with documentation of route of delivery. Exclusion criteria for this analysis included multiple gestations (n=31), incomplete first trimester computer-assisted telephone interviews (n=90), and no study ultrasound (n=76). The resulting population of 2,999 women had uniform assessment for leiomyomata and was at risk for cesarean birth. Only women identified as non-Hispanic White or non-Hispanic Black were included in our final investigation (n=2,635). Other racial groups were excluded due to small sample sizes (n=364). The Institutional Review Board of Vanderbilt University approved this study and all participants gave informed consent.

Variable Definitions

Route of delivery was obtained from medical and vital records. Our outcome was a dichotomous variable: women having a primary or repeat abdominal surgical delivery were considered to have a “cesarean birth” while all vaginal births, with or without forceps or vacuum assistance, were “vaginal” or “non-cesarean births.” Information regarding whether a cesarean was planned or performed as an emergency was not available.

To determine the presence or absence of leiomyomata, all women underwent a transvaginal ultrasound in the first trimester. The position, type, and size of each leiomyoma were documented by experienced, research trained, pelvic sonographers and confirmed by a study physician using methods that have been described [1]. RFTS includes leiomyomata as small as 0.5 centimeters (cm) in maximum diameter in their counts [1]. Leiomyoma volume (in cubic centimeters, cm³) was calculated from three diameter measures using the formula for an ellipsoid. In our primary analysis, leiomyoma presence was dichotomous. Women in whom no leiomyomata were detected were classified as “without leiomyomata” and those with one or more were classified as “with leiomyomata.”

Women join RFTS for many reasons, but recruitment was not targeted toward women with specific concerns about leiomyomata or pregnancy health, nor is RFTS advertised as a study of leiomyomata. Participation does not influence clinical care. As a courtesy, ultrasound results are sent to the practice or clinic indicated by each participant. In these materials, the sonographer indicated whether she suspected the presence of a leiomyoma, but the classification, measurements, and diagrams collected by RFTS are not released and the sonographers do not discuss findings with participants.

Women self-reported age (quartiles: <26 [reference], 26 and <29, 29 and <32, 32 years), race/ethnicity (non-Hispanic White, non-Hispanic Black), parity (nulliparous, 1, or 2+), date of last menstrual period (LMP), household income (<\$40,000, \$40,000-80,000, >\$80,000), and education level (high school, some college, 4 years of college) during computer-assisted telephone interviews. Race/ethnicity was obtained from vital records if not available from these interviews (n=3). The state (study site) in which a woman received prenatal care was also documented (North Carolina, Tennessee, or Texas). Gestational age at birth was determined as follows: from self-reported LMP if pregnancy dating conducted at the first trimester ultrasound was within +/- 7 days of the self-reported LMP, and from ultrasound estimates if gestational age by ultrasound differed by more than seven days from the self-reported LMP or if self-reported information was missing (n=348 and n=7, respectively). A body mass index (BMI) for each woman was calculated from standardized measures of

height and weight obtained at the ultrasound examination or from the first trimester interviews. BMI was classified according to World Health Organization and Institute of Medicine guidelines: underweight (BMI <18.5), normal weight (18.5 and <25.0 [reference]), overweight (25.0 and <30.0), or obese (≥30.0) [9].

Statistical Analysis

Descriptive summary data of maternal characteristics and all statistical analyses were generated with Stata/SE 12.0 (StataCorp, College Station, TX). Maternal characteristics were compared between women with and without leiomyomata; Pearson's chi-square test was used for categorical factors and the Wilcoxon rank-sum test was used for continuous measures ($\alpha=0.05$). Among women with leiomyomata, tumor characteristics were compared by mode of delivery, using similar tests.

For both unadjusted and adjusted analyses, generalized estimating equations (GEE) were used to calculate risk ratios (RRs) and 95% confidence intervals (CIs) for cesarean birth risk by leiomyoma presence or characteristics (log link function, binomial family). This method was used to control for correlation within the three study sites; we presumed an independent correlation structure. *A priori*, we considered maternal age, race, BMI, and parity to be candidate confounders. A confounder was retained for inclusion in the final model if an adjusted estimate for leiomyoma presence was more than 10% different from the unadjusted estimate. The final GEE models were adjusted for maternal BMI and age, with study site included as a grouping variable. Prior cesarean birth was considered to be an intermediate variable in a non-causal pathway between present leiomyoma status and cesarean birth, as a history of leiomyomata may be related to both a prior cesarean and the presence of a current leiomyoma. We examined risk of primary cesarean (no prior cesarean) as an alternate outcome of interest, rather than adjust for prior cesarean. Accordingly, we present results for both overall risk of cesarean birth and those limited to women at risk for primary cesarean birth (44 women with vaginal births after cesareans and 283 women with prior cesareans were excluded).

RESULTS

Among the 2,635 women, 785 had a cesarean birth (29.8%) and 295 women had one or more leiomyomata (11.2%). Women who had leiomyomata were more likely to be aged 32 or older, non-Hispanic Black, and overweight (BMI ≥ 26.0 and <29.0) or obese (≥29.0) than women without leiomyomata. Parity, gestational age at delivery, history of prior cesarean birth, household income, and education level were comparable between the two groups (Table 1).

Sonography did not identify any women with more than seven leiomyomata and total leiomyoma volume ranged from less than 1 cm³ to more than 420 cm³. In unadjusted analyses limited to women with leiomyomata, a greater number of leiomyomata and higher total leiomyoma volume were associated with cesarean birth (Table 2).

Leiomyoma presence was associated with an increase in cesarean birth risk prior to adjustment (RR 1.27, CI [1.17, 1.37]), but this association was attenuated with adjustment for maternal age and BMI (ARR 1.11, CI [1.02, 1.20]; Table 3). The adjusted risk associated with the presence of leiomyomata for having a primary cesarean (no previous cesarean) was similar (ARR 1.19, CI [1.04, 1.36]). The risk for primary cesareans were greater in magnitude than those for overall cesareans, but followed a similar pattern across the leiomyoma volume categories. To assess the influence of leiomyoma size and compare our results to previous studies, we compared women with single leiomyomata greater than 3 cm in maximum diameter (n=73) to those with no leiomyomata.¹⁰ Risk of cesarean birth was

increased for women with these “large leiomyomata” (ARR 1.22, CI [1.14, 1.32]). We also compared women with total leiomyoma volumes of less than 14 cm³, between 14 and 33 cm³, or greater than or equal to 33 cm³ to those with no leiomyomata. These cutoffs correspond roughly to a single spherical leiomyoma of less than 3 cm in diameter, 3-4 cm in diameter, and greater than or equal to 4 cm, respectively. The risk of cesarean increased with greater total volume, showing significantly elevated adjusted risk in the group with total volume ≥ 33 cm³ (ARR 1.59, CI [1.44, 1.76]).

DISCUSSION

Cesarean birth is common and associated with increased costs and morbidity for mothers. Increased risk for cesarean birth among women with leiomyomata has been observed [2]. Many studies evaluating this risk have retrospectively identified leiomyomata and/or used hospital-based populations. In our community-based prospective cohort with uniform use of research quality ultrasounds, women with leiomyomata had an unadjusted 27% increase in the risk of having a cesarean (37%) compared to women without leiomyomata (29%). After adjusting for confounding by maternal BMI and age, this risk was attenuated (ARR 1.11, CI [1.02-1.20]). The risk for cesarean birth was elevated for those women with larger single leiomyomata (ARR 1.22, CI [1.14-1.32]) or the largest total combined tumor volume (ARR 1.59, CI [1.44-1.76]).

These risk estimates are lower in magnitude than those found in many previous studies likely because of our inclusion of all women with leiomyomata and the use of RRs instead of ORs, the latter overestimating the former when the outcome is common. It is important to obtain these aggregate risk measures (not adjusted for causally-related complications) from general populations in order to assess the impact of leiomyomata on reproductive outcomes, such as cesarean birth.

Although the risks for certain complications associated with cesarean birth are concerning when comparing women with and without leiomyomata, current evidence does not suggest taking action to remove these tumors during pregnancy or as a prophylactic measure prior to conception, as these complications are rare and may be outweighed by the risks associated with myomectomy. For example, while Stout and colleagues (a large hospital-based retrospective cohort study) report a two-fold increase in the odds of placenta previa for women with leiomyomata, calculating an absolute risk difference shows an excess of 91 cases of placenta previa per 10,000 women [5]. Furthermore, if performing myomectomies on women with leiomyomata conferred a 22% reduction in cesareans (e.g., the cesarean prevalence in our leiomyoma group became that of our non-leiomyoma group), 13 women would need to have this surgery in order to prevent one cesarean (the “number needed to treat”) [11]. However, the risk of myomectomy-associated complications like uterine rupture or adhesion formation may deter any vaginal birth attempt in subsequent pregnancies and necessitate cesarean birth.

Larger size or greater number of leiomyomata has not always been associated with a higher risk or prevalence of cesarean birth [3,5]. This may be due to difficulty in comparing effects across studies and the potential for exposure misclassification when arbitrary cut-off points for size are chosen. Qidwai and colleagues retrospectively examined routine second trimester ultrasounds to identify leiomyomata one cm or larger among women delivering at the University of California, San Francisco (approx. n=15,100, leiomyoma prevalence of 2.7%). They reported no association between cesarean risk and a continuous measure of leiomyoma volume in a linear regression analysis, but specific results and models were not described [3]. A retrospective cohort study from Washington University, which documented the six largest leiomyomata found on second trimester ultrasounds (approx. n=64,000,

leiomyoma prevalence of 3.2%), did not observe an increased cesarean risk for women with leiomyomata larger than five cm compared to those with smaller ones [5]. When comparing to women without leiomyomata, they did see an increase in risk among women with a mean leiomyoma volume between 1-99 cubic millimeters, but not among women with a larger mean volume [5]. In these analyses, women with placenta previa or breech presentation were excluded. In a similar study from an Italian university hospital that limited their population to women with leiomyomata of five cm or larger (second trimester ultrasounds, n=24,500, prevalence of 1%), Vergani and colleagues concluded that maximum leiomyoma diameter was associated with cesarean birth before the onset of labor after adjusting for age, gestational age at delivery, uterine scarring, and fetal presentation [4]. We found that greater total leiomyoma volume was associated with cesarean birth, but tumor position or type may also influence this risk. Similar to previous studies, this association between tumor volume and cesarean birth risk may be due to both increased risk of complications with more severe disease or an underlying bias in clinical care that indicates surgery for larger or more numerous leiomyomata.

Leiomyoma position and size may affect placental and fetal positioning, as well as uterine vascular and contractile activity, and thereby increase the likelihood of needing a cesarean birth. The exact mechanism by which leiomyomata increase risk is not well understood. Aside from institutional criteria limiting which leiomyomata are documented, the size and type of each tumor may not always be recorded during routine ultrasounds. Both practices can lead to an inaccurate classification of exposure status and an inadequate description of the burden of leiomyomata within a study population. Due to small sample sizes and collinearity between leiomyoma size and position or type, we were not able to make a clean distinction between risks due to these characteristics in additional GEE analyses (results and further description of these analyses are presented in the supplementary materials).

The nature of our study allowed us to estimate the risk for leiomyoma-associated cesarean birth in a community-recruited, multi-state population. Our cohort represents a diversity of women, including Black women, living in or near urban areas in the southern United States. The burden of leiomyomata is high among reproductive-aged Black women, who comprised 20% of our study population [1].

By following women prospectively, we had the opportunity to systematically measure potential confounders and conduct standardized ultrasound screenings for the presence of leiomyomata in all participants. We would not know if leiomyoma characteristics changed in substantial ways between the first and last trimester, which is a common limitation of ultrasound studies, but which does not impair ability to address presence of leiomyomata and risk. We may be underestimating disease severity for women whose leiomyomata greatly change during pregnancy, but there is conflicting evidence regarding whether or not leiomyomata grow during this time [12-15]. Furthermore, because increasing fetus or uterine size can impede visualization later in pregnancy, our first trimester timing of ultrasounds is ideal for measuring and identifying leiomyomata (targeted for the sixth week of gestation).

Our primary purpose was to identify an overall risk for cesarean birth due to leiomyomata among a general population of reproductive aged women. Larger sample sizes would allow for further examination of risk due to tumor characteristics and information regarding medical indications for route of delivery and intention for a vaginal birth would enhance our discussion. Thus far, the literature on leiomyomata during pregnancy has provided an incomplete picture of the risk for cesarean birth. Ultimately, to fully understand the risk due to leiomyomata, studies must: use standardized screening in general populations; examine the influence of tumor characteristics (size, position, type); identify potential effect modification by cesarean electivity; and not adjust for potential causal intermediates.

CONCLUSION

Our data indicate that women with larger leiomyomata or greater total tumor volume were at increased risk for cesarean birth. More complete knowledge about leiomyoma characteristic-specific risks could inform decision making for leiomyoma treatment among women planning a pregnancy or allow clinicians to anticipate specific pregnancy and labor complications. Ultimately, use of data from large clinical consortia may be required to answer nuanced questions about leiomyoma characteristics and risk.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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LIST OF ABBREVIATIONS AND ACRONYMS

ARR	Adjusted risk ratio
AOR	Adjusted odds ratio
BMI	Body mass index
CI	Confidence interval
cm	Centimeter
cm³	Cubic centimeters
GEE	Generalized estimating equations
LMP	Last menstrual period
n	Number
OR	Odds ratio
P	P-value
RFTS	Right from the Start
RR	Risk ratio

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Table 1

Maternal Characteristics in Relation to Leiomyoma Status: Right from the Start, 2000-2010

Characteristics	No Leiomyomata (n=2,340)		Leiomyomata (n=295)		P
	n	%	n	%	
Age (y)					<0.001
<26	581	24.8	40	13.6	
26 and <29	490	20.9	46	15.6	
29 and <32	578	24.7	65	22.0	
32	691	29.5	144	48.8	
Missing	0		0		
Race/Ethnicity					<0.001
Non-Hispanic White	1,910	81.7	182	61.7	
Non-Hispanic Black	427	18.3	113	38.3	
Missing	3		0		
BMI					<0.001
Underweight	57	2.4	4	1.4	
Normal weight	1,326	56.8	129	43.7	
Overweight	533	22.8	81	27.5	
Obese	418	17.9	81	27.5	
Missing	6		0		
Parity					0.614
Primiparous	1,088	46.9	137	46.8	
1	822	35.5	98	33.5	
2+	409	17.6	58	19.8	
Missing	21		2		
Gestational Age at Delivery (wk)					0.477
median		39.6		39.6	
[range]		[24.1-45.1]		[23.0-43.4]	
Missing	0		0		
Prior Cesarean Birth					0.116
Yes	282	12.1	45	15.3	
No	2,050	87.9	249	84.7	
Missing	8		1		
Household Income					0.186
\$40,000	616	27.2	68	23.6	
\$40,000-80,000	879	38.8	107	37.2	
\$80,000	772	34.1	113	39.2	
Missing	73		7		
Education Level					0.226
High school	356	15.2	35	11.9	
Some college	424	18.1	50	17.0	
4 years college	1,560	66.7	210	71.2	

Characteristics	No Leiomyomata (n=2,340)		Leiomyomata (n=295)		<i>P</i>
	n	%	n	%	
Missing	0		0		
Study Site					<0.001
North Carolina	1,792	76.6	250	84.8	
Texas	170	7.3	3	1.0	
Tennessee	378	16.2	42	14.2	
Missing	0		0		

n=number; y=years; BMI=body mass index; wk=weeks

Table 2

Leiomyoma Characteristics in Relation to Mode of Delivery: Right from the Start, 2000-2010

Leiomyoma Characteristics	Cesarean (n=108)		Vaginal (n=187)		<i>P</i>
	n	%	n	%	
Volume					
Number					
median		1.0		1.0	0.018
[range]		[1-7]		[1-6]	
Total volume * (cm ³)					
median		10.5		4.5	0.004
[interquartile range]		[1.5-31.8]		[0.9-18.0]	
Categorical					
<14	63	31.7	136	68.3	0.006
14 and <33	18	37.5	30	62.5	
33	27	56.3	21	43.8	
Largest leiomyoma volume * (cm ³)					
median		7.9		4.3	0.010
[interquartile range]		[1.4-24.7]		[0.8-15.0]	
Categorical					
<14	65	32.0	138	68.0	0.031
14 and <33	22	42.3	30	57.7	
33	21	52.5	19	47.5	

n=number; cm³=cubic centimeters* A volume of 14 cm³ is roughly equivalent to one spherical leiomyoma 3 cm in diameter; 33 cm³ corresponds to a leiomyoma 4 cm in diameter

Table 3
Cesarean Birth Risk by Leiomyoma Characteristics: Right from the Start, 2000-2010

Model	n	Unadjusted RR	95% CI	Adjusted* RR All Cesareans	95% CI	n	Adjusted* RR Primary Cesareans Only	95% CI
No leiomyomata	2,340	1.00	Reference	1.00	Reference	2,050	1.0	Reference
Leiomyoma presence (any)	295	1.27	1.17, 1.37	1.11	1.02, 1.20	249	1.19	1.04, 1.36
Single leiomyoma, 3cm diameter	73	1.37	1.26, 1.50	1.22	1.14, 1.32	60	1.34	1.10, 1.64
Total Volume (cm ³) [†]								
<14	199	1.09	0.98, 1.22	0.97	0.89, 1.06	170	0.95	0.81, 1.12
14 and <33	48	1.30	1.09, 1.54	1.18	0.87, 1.60	39	1.19	0.88, 1.60
33	48	1.94	1.80, 2.10	1.59	1.44, 1.76	40	2.20	1.77, 2.72

n=number; RR=risk ratio; CI=confidence interval; REF=reference group; cm³=cubic centimeters

Women without leiomyomata served as the reference group for each of the three models

* Adjusted for maternal body mass index and age

[†] A total volume of 14 cm³ is roughly equivalent to one spherical leiomyoma 3cm in diameter; 33 cm³ corresponds to a leiomyoma 4 cm in diameter