Impact of a Potential 20-Week Abortion Ban on Likelihood of Completing Required Views in Second-Trimester Fetal Anatomy Ultrasound

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Abstract	Objective The aim of this study was to quantify the likelihood of assessing all mandated fetal views during the second-trimester anatomy ultrasound prior to the proposed federal 20-week abortion ban. Study Design Retrospective cohort study of a random sample of 1,983 patients undergoing anatomy ultrasound in 2017 at a tertiary referral center. The difference in proportion of incomplete anatomic surveys prior compared with after 20-week gestation was analyzed using X^2 and adjusted logistic regression; difference in mean days elapsed from anomaly diagnosis to termination tested using <i>t</i> -tests and survival analysis.
 Keywords termination health policy ultrasound fetal anomaly abortion antenatal care 	Results Incomplete views were more likely with initial ultrasound before 20 weeks (adjusted relative risk: 1.70; 95% confidence interval: 1.50–1.94); 43.5% versus 26.1% were incomplete before and after 20 weeks, respectively. Fetal structural anomalies were identified in 6.4% ($n = 127/1,983$) scans, with 38.0% ($n = 49$) identified at follow-up after initial scan was incomplete. 22.8% ($n = 29$) with an anomaly terminated. Conclusion A complete assessment of fetal views during an anatomy ultrasound prior to 20-week gestation is often not technically feasible. Legislation limiting abortion to this gestational age would greatly impact patient's ability to make informed choices about their pregnancies.

Key Points

- It is often not technically possible to complete anatomy ultrasound prior to 20-week gestation.
- Often, anomalies are missed during early, incomplete anatomy ultrasounds.
- After the diagnosis of a structural anomaly, one in five chose to terminate the pregnancy.

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The American College of Obstetricians and Gynecologists recommends patients with low-risk pregnancies undergo two sets of ultrasounds, one at 12 weeks and another between 18 and 22 weeks.¹ The latter scan, colloquially termed the "anatomy ultrasound," is used to evaluate developing fetal anatomy, particularly the cardiac and central nervous organ systems. While the American Institute of Ultrasound in Medicine (AIUM) and other prenatal societies provide guidelines regarding the mandated fetal anatomy structures that should be evaluated at the time of secondtrimester anatomy surveys, limitations due to early gestational age, maternal body habitus, placental location, and fetal position are known to limit the technical feasibility and accuracy of prenatal sonography.¹ As such, as many as onethird of patients require repeat ultrasounds for full anatomic evaluation^{2,3}

Information elucidated during second-trimester antenatal screening influences management of the pregnancy including antenatal consultation with genetics and pediatric specialists; some may ultimately elect to terminate a pregnancy. Approximately 3 to 4% of all pregnancies are complicated by structural birth defects and the proportion choosing to terminate a pregnancy based on a prenatally diagnosed anomaly varies widely across studies.^{4,5} Fetal anomalies diagnosed in the second trimester are a common reason for second-trimester pregnancy terminations.^{6,7} In contrast to pregnancy terminations following the diagnosis of fetal aneuploidy, which, with new screening technologies such as cell-free fetal DNA/noninvasive prenatal testing, can be done earlier in pregnancy, the timing of pregnancy terminations for structural abnormalities has not changed substantially over the last two decades.^{8,9}

Patients with a diagnosis of fetal anomaly in the secondtrimester often experience delays in termination.^{10,11} This research suggests time may be a critical factor in decisionmaking for second-trimester abortion due to fetal anomaly and may be limiting due to logistics, access to providers, and gestational-age limits.

In the last 2 years, federal bills introduced in Congress would criminalize pregnancy termination provision after 20 weeks.¹² Currently, 20 states already ban pregnancy terminations after 20 weeks, with 17 of these laws enforced.¹³ Research conducted in these states shows these bans may be severely limiting patients' options, forcing patients to continue pregnancies or travel elsewhere for abortion services.^{14,15} As has historically been the case with abortion policy, the impact of these bans is concentrated among patients with lower resources, with income, insurance status, and distance to clinic shown to disproportionately affect access.^{16–18} The U.S. Supreme Court recently agreed to hear Dobbs versus Jackson Women's Health Organization that will consider whether states can ban abortion before viability.¹⁹ The Mississippi law in dispute bans abortions at 15 weeks. The ruling on this case will have farreaching consequences for those seeking abortions in the second trimester.

In the context of this legislative environment, we sought to evaluate the potential impact of a 20-week ban on patients seeking abortion due to fetal anomalies in a currently nonrestrictive environment. Ultimately, we sought to determine the utility of offering earlier second-trimester screening ultrasounds by determining the likelihood of completing all mandated fetal views prior to 20-week gestation.

Materials and Methods

This retrospective cohort study evaluated patients completing a Level II anatomy ultrasound between January 1, 2017 and December 31, 2017 at one of the seven Lucile Packard Children's Hospital (LPCH) Stanford Perinatal Diagnostic Centers across Northern California, which are certified by the AIUM. These locations conduct anatomy ultrasounds for both routine screening in low-risk pregnancies as well as in high-risk pregnancies where a fetal anomaly may be suspected.

All second-trimester fetal anatomy surveys are conducted initially by American Registry for Diagnostic Medical Sonographers (RDMS)-certified sonographers and verified in-person by either board-certified maternal-fetal medicine specialists or pediatric radiologists with expertise in fetal sonography. During the study period, all exams were conducted using General Electric Voluson E8 Expert ultrasound machines (GE Healthcare Austria GmbH & Co OG, Zipf, Austria) and the outcomes reported using ClickView reporting software. For all fetal anatomy surveys, complete views were defined by a preset electronic checklist (a "scan assistant" feature) of mandated images with optimal views based on AIUM guidelines as a part of an ongoing sonography quality assurance project.^{20,21} Any time one or more fetal structures is not optimally visible, the ultrasound is considered incomplete, and the patient is asked to return to complete the anatomic survey. Following sonographic detection of a structural defect, patients are referred to the LPCH Fetal Center for genetic counseling and additional multidisciplinary consultations.

We included all ultrasounds coded as "Screening Anatomy Ultrasound" in the year 2017. To account for incomplete charts, a computerized random numbers generator selected a sample of 2000 patients that comprised our cohort. Ultrasounds were excluded if they occurred prior to 16-week gestational age.

To quantify the impact of a 20-week ban on patients diagnosed with fetal anomalies in the second-trimester, our primary outcome was the proportion of ultrasounds with an incomplete anatomy evaluation before versus after 20-week gestational age. Our secondary outcome of interest was time, in days, from diagnosis to abortion for those that chose to terminate.

Based on a prior study where an initial ultrasound was incomplete in 14% of individuals at a median gestational age of 18.5-week gestation,²² a power calculation for a two-sided unpaired *t*-test determined we would need 826 patients per group to exclude a clinically meaningful difference of more than 5% in incomplete views comparing greater than 20-week gestation.

We reviewed the medical record for the gestational age at anatomy ultrasound, presence of completed anatomy per AlUM Guidelines,²¹ gestational age at subsequent required imaging, type of anomaly, and pregnancy outcome. We defined fetal anomaly based on the National Birth Defects Prevention Network's 47 major anomalies.²³ For this analysis, scans in which an isolated fetal soft marker was identified were not included as anomalous. We also evaluated whether an anomaly had previously been suspected at an outside clinic, and the gestational age at time of that referral. Other demographic variables collected included maternal age, parity, and insurance status. Distance traveled to clinic, in miles, was approximated for the centroid of the patients' zip code to the precise location of the Perinatal Diagnostic Center visited using SAS functionality.

Prior to data abstraction, we obtained exemption from the Stanford University Institutional Review Board (IRB-45082). We sought a waiver of consent as anonymized records resulted in no more than minimal risk to the subjects. This project and manuscript adhere to applicable Strengthening the Reporting of Observational Studies in Epidemiology guidelines to ensure appropriate presentation of research methodology and interpretation.²⁴

Study data were abstracted from an electronic medical record and managed using the Research Electronic Data Capture tool hosted by Stanford University.²⁵ Categorical data are presented as percentages and differences reported using X² using SAS OnDemand for Academics (SAS Institute Inc., Cary, NC). Multiple logistic regression was used to assess the likelihood of incomplete ultrasound based on gestational age adjusting for maternal age, parity, insurance, and clinic location. In those with a diagnosed fetal anomaly choosing termination, a survival analysis was performed to compare time elapsed from initial ultrasound to abortion between those with initial ultrasound before 20-week gestation to those after 20-week gestation with log-rank testing of the null hypothesis. Linear regression confirmed maternal age, parity, insurance, and clinic location did not influence time elapsed from ultrasound to termination and thus, we present an unadjusted survival analysis. For all the analyses, p-values of <0.05 were considered significant.

Results

In the 2017 calendar year, 5,951 ultrasounds were coded as "Screening Anatomy Ultrasound." Using a computerized random numbers generator, we selected a sample of 2000 pregnancies for review, of which, a total of 17 ultrasounds occurred prior to 16-week gestation and were thus excluded. One-hundred eight (5.4%) patients were referred for a suspected prior anomaly from an outside institution, while 1,875 (94.6%) had ultrasounds as part of regularly scheduled prenatal care.

In total, 701 anatomy ultrasounds occurred before 20 0/7week gestation and 1,282 anatomy ultrasounds occurred after or at 20 0/7-week gestation. Among both groups, the median patient age was 29 years old and the majority had no prior pregnancies and private insurance. Distance to Perinatal Diagnostic Center differed significantly between those with an initial anatomy ultrasound prior to 20 weeks comTable 1Baseline demographics of those presenting foranatomy ultrasound before compared with after 20-weekgestational age

	Initial ultrasound < 20 weeks (n=701)	Initial ultrasound > 20 weeks ($n = 1,282$)	<i>p</i> -Value
Maternal age (y)			0.95
< 18	8 (1.1)	11 (0.9)	
19-<25	86 (12.3)	154 (12)	
26-<35	417 (59.5)	781 (61.0)	
36-<40	154 (22)	271 (21.2)	
>40	36 (5.1)	63 (4.9)	
Parity			0.39
0	264 (41)	388 (37.1)	
1	211 (32.8)	353 (33.8)	
2	101 (15.7)	172 (16.5)	
3	46 (7.1)	79 (7.6)	
>4	22 (3.4)	52 (5)	
Insurance			0.07
Private	460 (65.6)	773 (60.4)	
Medi-Cal	238 (33.9)	501 (39.2)	
Other	3 (0.4)	5 (0.4)	
Distance to clinic (mi)			<0.001
< 24.9	591 (84.4)	968 (75.7)	
25-<49.9	76 (10.9)	231 (18.1)	
50-<99.9	16 (2.3)	57 (4.5)	
>100	17 (2.4)	22 (1.7)	

Data are *n* (%).

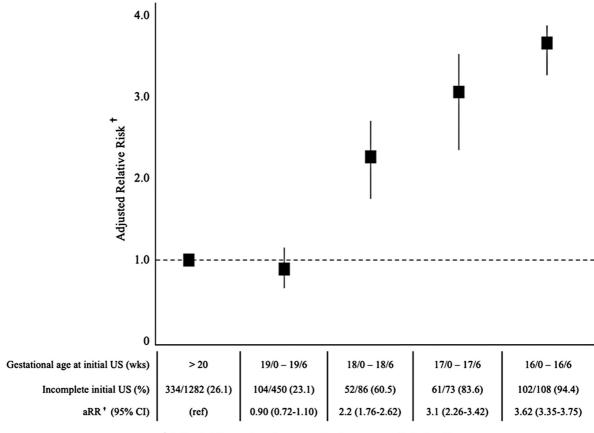
Statistical analysis: X^{2.}

pared with after 20 weeks, with people living within 25 miles of the ultrasound clinic more likely to present prior to 20-week gestation than those living at greater distances (**Table 1**).

Incomplete fetal views were more likely to occur in those who had their initial ultrasound before 20 0/7-week gestation compared with those whose initial ultrasound at or after 20 0/7 weeks (adj risk ratio 1.70 [95% confidence interval [CI]: 1.50-1.94] p < 0.0001; 43.5% versus 26.1%, respectively). For those initially presenting prior to 20-week gestation, the risk of incomplete initial views increased at earlier gestational ages (p for trend <0.001) (**–Fig. 1**).

For scans that remained incomplete even after repeat views, maternal obesity was cited as a significant cause of suboptimal views in 43.2% (n = 96) of cases. Other patients with incomplete scans were lost to follow-up (n = 110, 49.6%), with these patients significantly more likely to hold public insurance (odds ratio [OR]: 2.56 95% CI: 1.72–3.82) and live greater than 25 miles from perinatal diagnostic center (OR: 2.22 95% CI: 1.35–3.65).

The overall proportion with fetal anomalies was 6.4% (n = 127), with 38.0% (n = 49) of these anomalies identified in a follow-up ultrasound after the first was suboptimal. The most common anomalies identified were cardiac (34.7%,



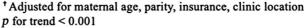


Fig. 1 Adjusted relative risk (aRR) of incomplete ultrasound based on gestational age at initial ultrasound compared with those presenting after 20-week gestation. CI, confidence interval; US, ultrasound.

n = 44) and central nervous system (20.5%, n = 26) (**>Table 2**).

Of those for whom an anomaly was identified, 22.8% (n=29) terminated the pregnancy. Excluding one termination at 26 2/7 weeks due to anomalies not compatible with life, terminations occurred at a median gestational age of 21 6/7 weeks (range: 171/7-240/7 weeks). The mean amount of time between ultrasound and pregnancy termination for those with an initial ultrasound prior to 20 weeks was 14 days (interquartile range: 5-22 days), while those with an initial ultrasound after 20 weeks had a mean delay of 6 days (interquartile range: 5–8 days) (log-rank p = 0.043) (**Fig. 2**). When restricting to those with anomalies identified at first scan (n = 12), the discrepancy in time to abortion was even greater, with patients terminating 23 days (interquartile range: 12-34 days) after the scan if occurring before 20-week gestation, compared with 7 days (interquartile range: 5-12 days) if scan occurring after 20-week gestation (p = 0.025).

before 20-week gestation resulted in high rates of incomplete exams. About 38.0% of our diagnosed fetal anomalies were not identified at the initial ultrasound and were diagnosed at a requested follow-up scan. This builds upon

Table 2 Incidence of anomalies and pregnancy outcome					
	Continued (n=91)	Termination (n = 29)			
Type of anomaly					
Central nervous system	20 (22.0)	5 (17.2)			
Cardiac	36 (39.6)	6 (20.7)			
Orofacial	4 (4.4)	3 (10.3)			
Gastrointestinal	11 (12.1)	5 (17.2)			
Genitourinary	9 (9.9)	3 (10.3)			
Musculoskeletal	9 (9.9)	6 (20.7)			
Chromosomal	2 (2.2)	1 (3.5)			

Abbreviations: CNS, central nervous system; MSK, musculoskeletal Data are n (%)

Discussion

In this sample of people seeking routine fetal anatomy scans within a large tertiary care network, ultrasounds performed

Note: There were three pregnancies for whom outcomes were unknown. There were four pregnancies in which fetal demise occurred (one fetus with CNS anomalies, one with MSK anomalies; two fetus with chromosomal anomalies).

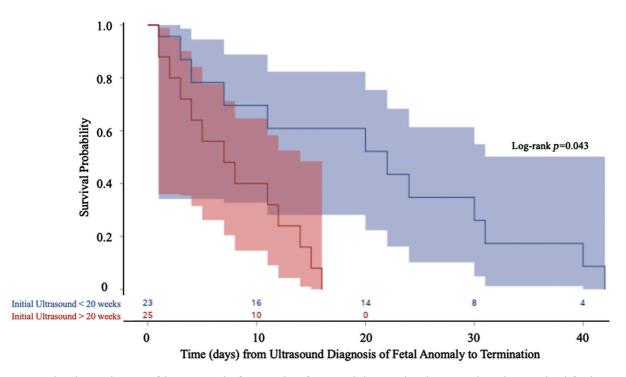


Fig. 2 Survival analysis with 95% confidence intervals of time, in days, from initial ultrasound to abortion in those diagnosed with fetal anomaly, comparing those with initial ultrasound before 20-week gestation to those after 20-week gestation.

existing literature that earlier ultrasounds are more likely to result in suboptimal fetal views.²⁶ Ultimately, our research suggests results of the anatomy scan may be critical to patients' decision-making: of those diagnosed with a fetal anomaly, approximately one in five chose to terminate the pregnancy based on this information.

This study builds on existing data that suggests completing the anatomy ultrasound prior to 20 weeks is technically challenging and often incomplete. In a large retrospective review of 40,335 pregnancies at 18 to 21 6/7 weeks, 29% required at least one follow-up sonogram for incomplete views.³ Earlier in the second-trimester, incomplete examination of fetal anatomy was reported in over half of scans at 11 to 14 weeks.²⁷ Although it may be possible to document normal structures earlier in the second trimester, AIUM guidelines do not recommend routine fetal survey prior to 18-week gestation as structures can be difficult to visualize because of fetal size, position, movement, abdominal scars, and maternal abdominal wall thickness.²⁸

If ultrasounds performed before 20 weeks are significantly more likely to result in incomplete views, this brings into question patients' ability to make informed decisions in the setting of a 20-week abortion ban. When Georgia passed a 22week abortion ban in 2012, the total number of abortions at 21 weeks or less remained stable from the 5 years prior to the 5 years after the implementation; however, the number of abortions at more than 21 weeks declined.¹⁵ It is concerning that the number of abortions at earlier gestational ages did not increase as the ban went into effect, suggesting that these patients were either forced to continue the pregnancy or travel elsewhere to get their abortion. Indeed, in a recent systematic review, exceeding local clinic or state-based gestational age limits was a primary cause of needing to travel long distances for abortion services, often crossing state or country borders to seek care.²⁹

In our study, nearly half of incomplete studies were attributed to maternal habitus due to increased body mass index (BMI). Notably, we were unable to abstract BMI from the medical record, but we noted when incomplete views were secondary to body habitus as ascribed by ultrasonographer. This finding is corroborated by other studies of the anatomy ultrasound: a prospective cohort study found that those with higher BMI (between $30-34.9 \text{ kg/m}^2$) were 6.5times more likely to require a further appointment for repeat views.³⁰ This is particularly concerning as obesity in pregnancy $(>30.0 \text{ kg/m}^2 \text{ BMI})$ increases the odds of having an anomalous fetus, and that the incidence of obesity in pregnancy is increasing nationwide.³¹ Our catchment area typically has lower BMI compared with the rest of the country.³² This effect may be exaggerated in other areas where obesity even higher and compounded where abortion more limited.

After the initial diagnosis of an anomaly on ultrasound, additional imaging and genetic testing are often required to confirm a fetal diagnosis. Even if a patient is able to get complete information about a structural fetal birth defect, the time required to arrange for and obtain a second-trimester abortion may be limiting in the setting of a gestational age abortion ban. This may be especially limiting in areas when people have to travel to a second-trimester provider.

As was the case in Georgia, the language around 20-week abortions remains misleading. Bans on abortion vary stateto-state, with some defining gestational age based on date of conception versus the standard medical practice of using last menstrual period (LMP). The federal bill that inspired this study, "Pain Capable Unborn Child Protection Act," would technically have banned abortions after 22-week gestation (as defined by LMP) but was publicized and interpreted in the media—and likely among patients—as a 20-week gestational age ban on abortions. Dating by conception reflects an ideologic preference and is an intentional and political shift in language meant to mislead patients. Our study, which defines gestational age based on LMP, reflects the consequences for pregnant people in the context of this confusing landscape.

We found that the median amount of time between ultrasound and abortion was 7 days, comparable to data from another academic tertiary-care center in Northern California.⁷ Importantly, we found the median amount of time between ultrasound and abortion was significantly shorter in those that had an initial ultrasound after 20week gestation compared with those with an initial ultrasound before 20 weeks. While our study methods limit conclusive interpretation of this difference, we suspect the difference in time from initial ultrasound to termination to be multifactorial. In the over 20-week group, some individuals were already faced with making expedited decisions regarding their pregnancies with the existing viability limit. The qualitive experience of people making these decisions approaching a gestational age limit is worthy of further study. We suspect the need for repeat ultrasounds in the prior to 20-week group may be a part of the delay from initial ultrasound to termination. In nonrestrictive states, clinicians may consider routinely scheduling anatomy ultrasounds at or after 19 weeks to limit repeat ultrasound while also maintaining the option to terminate.

Recently, a study analyzing the utility of repeat ultrasounds for anomaly detection suggested the yield of repeat ultrasounds may be low, with over 90% of anomalies detected on initial surveys and appreciably more scans required for detection of remaining anomalies.²² Yet, in our cohort, of the total anomalous fetuses identified, 38.0% were noted in a follow-up ultrasound after the first was suboptimal or incomplete. As one in five individuals with an identified anomaly went on to terminate their pregnancy, we support repeating ultrasounds in an attempt to work toward complete views.

The generalizability of this study may be limited beyond the geographic area in which it was conducted. In a study of Medicaid funded abortions in California, four out of five traveled less than 50 miles for a second-trimester abortion.³³ The availability to proceed with termination in the second-trimester may also be overrepresented in this sample as California's public insurance option covers abortion. Finally, our specific institution has access to services and resources that may streamline time from diagnosis to termination, suggesting the median amount of time from diagnosis to termination may be an underestimate, particularly outside of a tertiary referral network where this study was completed.

A 20-week abortion ban would restrict access to pregnancy termination care at a crucial decision-making time in the pregnancy. This study demonstrates that moving the anatomy ultrasound earlier in the pregnancy is not technically feasible and would likely miss a significant number of anomalies. A 20-week ban may especially impact obese people; these individuals are more likely to have an anomalous fetus and are less likely to have a complete view prior to 20 weeks. As one in five in our cohort with an identified anomaly chose pregnancy termination, the information from the completed anatomy ultrasound is valuable for those attempting to make an informed decision about their pregnancies.

Note

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Conflict of Interest

None declared.

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