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Detailed Fetal Anatomic Ultrasound Examination

Effect of the 2014 Consensus Report on a Tertiary Referral Center

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Abstract: This study evaluates the impact of extended cardiac views on examination time, repeat imaging, and anomaly detection before and after implementation of 76811 guidelines (American Institute of Ultrasound in Medicine Consensus 2014). It is a retrospective study of singleton pregnancies undergoing detailed ultrasound imaging at 18 weeks' gestation or greater before and after the protocol change in an academic, tertiary care fetal center. Views required prior to 2014: 4-chamber, left outflow tract, right outflow tract. Additional views required after 2014: bicaval, aortic arch, 3-vessel, and 3-vessel trachea. Fetuses with known anomalies were excluded. Rates of detection of congenital heart disease (CHD), examination completion, repeat examination recommendation, fetal echocardiogram recommendation, completion by body mass index, and cardiac examination time were determined. Six hundred twenty-four subjects were included, 217 before and 407 after protocol change. Views obtained were as stated in the American Institute of Ultrasound in Medicine/Society for Maternal-Fetal Medicine consensus. Detection of CHD was not improved. Examination times increased by 20% (6.4 vs 7.7 minutes, $P < 0.05$). Number of incomplete studies increased by 130% (11% to 26%, $P < 0.05$). Twice as many patients were referred for repeat examination (6% vs 13%, $P < 0.05$). Completion rates were negatively correlated with body mass index. Recommendations for fetal echocardiogram were unchanged (5% vs 6%, $P = 0.6$). Additional imaging did not increase detection rate of CHD (3% vs 2%, $P = 0.3$). Extended cardiac views resulted in increased examination time, more incomplete examinations, and more repeat examinations without changing detection rates of CHD.

Key Words: 76811 exam, congenital heart disease, fetal anatomic ultrasound, fetal cardiac screening

Congenital heart disease (CHD) is among the most common fetal malformations, with an incidence approaching 9.1 per 1000 live births over the past 15 years,[1] representing nearly one third of all major congenital malformations.[2] Nationwide, fewer than 50% of severe CHD cases are detected prenatally, despite attempts to improve detection in a variety of ways.[3] Nearly 40% of babies with CHD require intervention after birth.[4] Those with critical CHD require urgent intervention/treatment within the first 24 hours of life.[5] Prenatal detection of specific types of CHD is accomplished by antenatal ultrasound examination and may improve neonatal morbidity and mortality.[6–11]

In 2013, the cardiac views required for routine screening by the American Institute of Ultrasound in Medicine (AIUM), American College of Radiology, American College of Obstetrics and Gynecology, and Society of Radiologists in Ultrasound included the 4-chamber view (4CV), left ventricular outflow tract (LVOT), and right ventricular outflow tract (RVOT) views.[12] In February 2014, the AIUM and the Society for Maternal-Fetal Medicine published a consensus report expanding the recommended cardiac views obtained on a high-risk screening ultrasound examination (76811 billing code).[13] This document changed practice by adding the aortic arch (AA), bicaval (superior vena cava [SVC]/inferior vena cava [IVC]), 3-vessel (3VV), and 3-vessel trachea (3VT) views to high-risk obstetric ultrasound examinations. Critical CHD, including transposition of the great arteries, hypoplastic left heart with intact atrial septum or restrictive foramen ovale, critical pulmonary stenosis/atresia, critical aortic stenosis/atresia, and obstructed total anomalous pulmonary venous return are among the most commonly diagnosed congenital heart disorders requiring urgent postnatal treatment. Some of these conditions may be more easily detected with the addition of the AA, SVC/IVC, 3VV, and 3VT views. The purpose of this study was to evaluate the impact of extended cardiac views on examination time, repeat imaging, and anomaly detection before and after implementation of AIUM/Society for Maternal-Fetal Medicine 76811 consensus recommendations.

MATERIALS AND METHODS

The study population included women with singleton pregnancies at 18 weeks' gestation or greater undergoing detailed fetal anatomic ultrasound at a university-associated fetal ultrasound center. Women referred to our center are a combination of university faculty and resident clinic patients, as well as women referred from outside clinics. All women referred for a screening examination were included in this study. Typically,
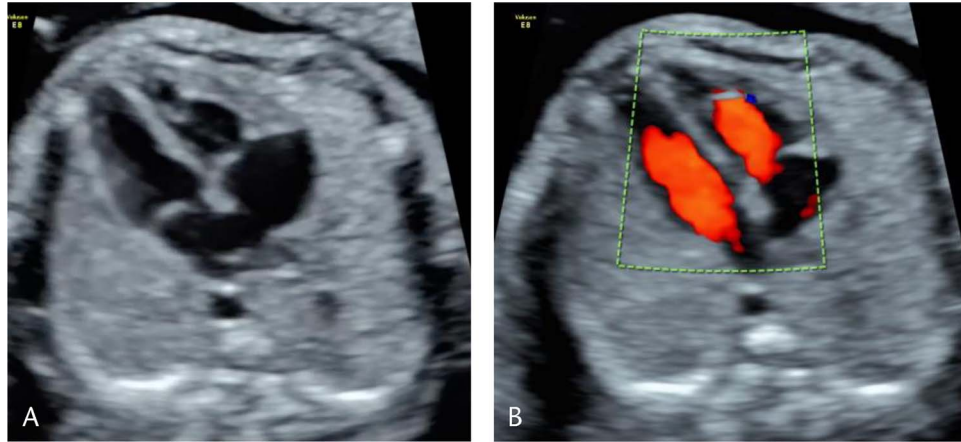
FIGURE 1. Normal 4CV at 22 weeks. A, Gray-scale image. B, Color Doppler image.

80% of women at our center would meet criteria for a 76811 examination, with the remainder being low risk. Women are examined using the same ultrasound protocol regardless of their risk category, and results are reported in the same way. Thus, we are effectively performing a detailed screening examination on all women who present to our center. As this investigation focused on use of the 76811 examination as a screening tool, women with known fetal cardiac anomalies were excluded. Charts were retrospectively reviewed in 2 groups. Group 1 (basic protocol) consisted of consecutive patients presenting 1 month prior to the adoption of the new 76811 guidelines. Group 2 (extended protocol) consisted of consecutive patients presenting 1 year after the adoption of the 76811 guidelines, to allow for sonographer and sonologist comfort with the new views. Approval for this study was obtained from the Human Research Protections Program (institutional review board) at our institution.

All patients presenting for an initial ultrasound examination in the second or third trimester receive a detailed fetal anatomic ultrasound examination with specified cardiac views according to our facility's established protocol. After publication of the 76811 consensus report in 2014, our facility's protocol was updated to adhere to the published consensus. Cardiac views obtained according to the protocol prior to May 2014 included the 4CV, LVOT, and RVOT (Figs. 1–3). The 3VV or 3VT views were also often obtained. Additional views obtained after the protocol change included AA, SVC/IVC, 3VV, and 3VT views (Figs. 4–7).

All examinations were completed at UCSD Fetal Care and Genetics (San Diego, Calif), using high-resolution ultrasound equipment (Voluson E8 or E10; GE Healthcare, Milwaukee, Wis). All examinations were performed by 10 fetal trained sonographers, of which one had advanced cardiac training. Scans were interpreted by perinatologists and radiologists with specialization in fetal ultrasound.

According to our group practice, images were acquired as static and cine loops, with and without color Doppler interrogation. In the extended protocol group, repeat examination was generally not recommended to complete views of the AA and the SVC/IVC views as long as no anomalies were suspected. Repeat examination was generally not recommended to complete anatomy in the third trimester. Repeat examination to complete anatomy was limited to 1 additional visit. Additional attempts to clear anatomy could be made at any repeat examinations scheduled for other reasons (eg, growth). Fetal echocardiogram referrals were placed for suspected cardiac anomalies or other risk factors for CHD (such as prior infant born with CHD, or maternal CHD).

Data were retrospectively abstracted by trained personnel. Gestational age was reported in weeks and was based on
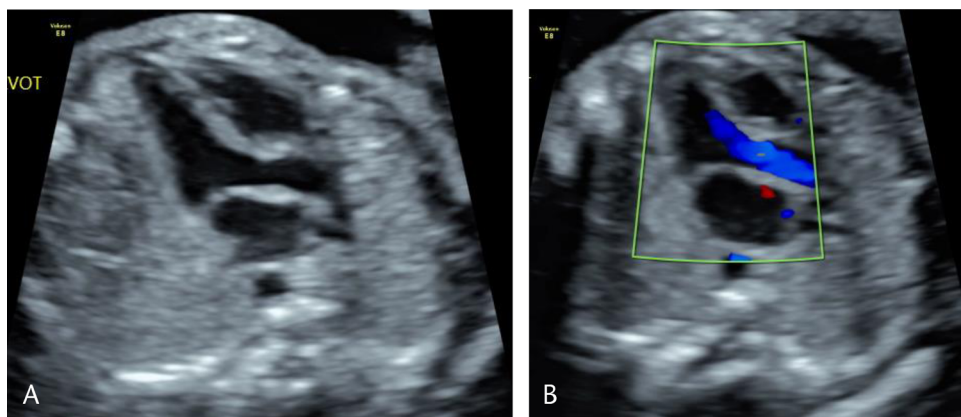
FIGURE 2. Normal LVOT at 22 weeks. A, Gray-scale image. B, Color Doppler image.
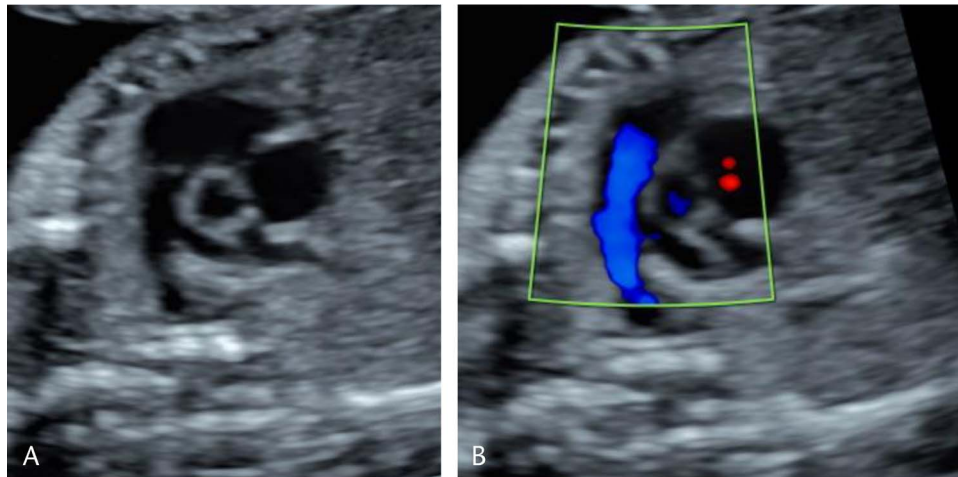
FIGURE 3. Normal RVOT at 22 weeks. A, Gray-scale image. B, Color Doppler image.

assigned dating. Maternal body mass index (BMI) was based on information available at date of scan. The clinical report was used to determine whether cardiac views were cleared. Views were called "complete" at the discretion of the interpreting physician if cardiac structures for those views could be adequately evaluated, and were graded as normal or abnormal. Presence or absence of color images was also collected for each cardiac view. Cardiac examination time was determined using the time stamp on cardiac images, subtracting time for intervening non-cardiac images. An examination was considered incomplete if any cardiac views were not completed according to the protocol in place at the time of scan. A recommendation for repeat examination was recorded if the repeat examination was recommended to complete cardiac anatomy.

The primary outcomes were cardiac examination time, rate of examination completion, and rate of repeat examination recommendations in the basic protocol and extended protocol groups. Secondary outcomes included examination completion rate in obese women, rate of fetal echo recommendation, and detection rate of cardiac anomalies in the basic and extended protocol groups.

Data analysis was performed using IBM SPSS statistics version 24.0 (Armonk, NY). χ^2, Student t test, Fisher exact, analysis of variance, and Mann-Whitney U test were used as appropriate. Statistical significance was set at $P < 0.05$.

RESULTS

A total of 624 subjects were included: 217 in the basic protocol group and 407 in the extended protocol group. Demographic information for the cohort is described in Table 1. There were no clinically significant differences between the 2 groups. Twenty-seven percent of the basic protocol group and 22% of the extended protocol group had no high-risk indication ($P = 0.2$). Removal of these women from the analysis did not affect the demographic, primary outcome, or secondary outcome data (data not shown). Gestational age in the basic protocol group was 6 days later than the extended protocol group. This difference is not felt to be clinically significant and may be a result of encouragement to refer patients for initial anatomy scan at an earlier time, to allow time for a repeat examination before 24 weeks, or because of parental concern.
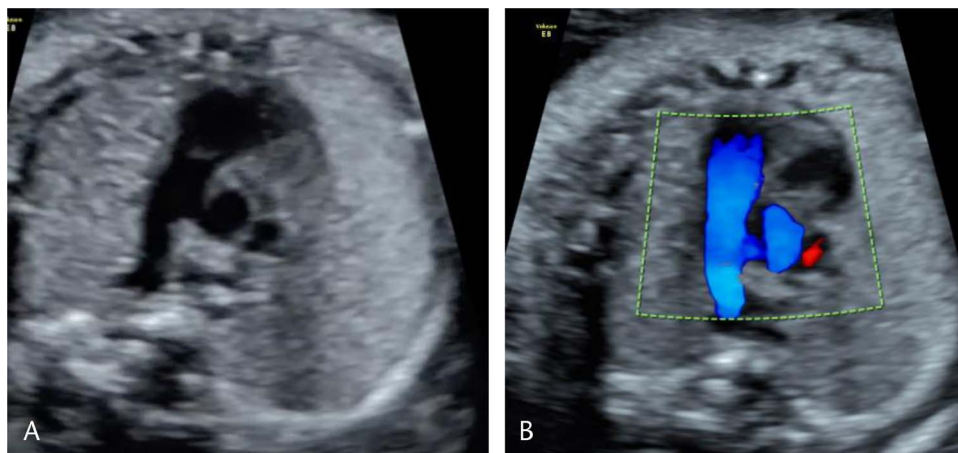
FIGURE 4. Normal 3V at 30 weeks. A, Gray-scale image. B, Color Doppler image.
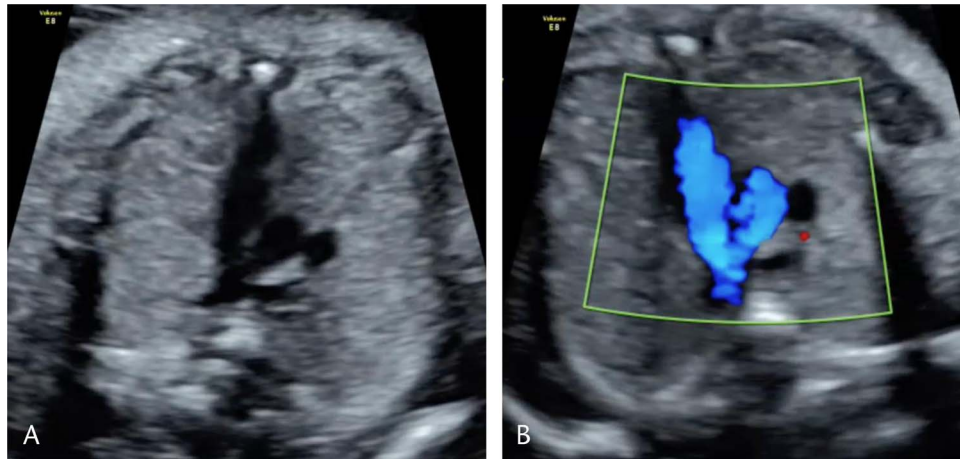
FIGURE 5. Normal 3VT view at 30 weeks. A, Gray-scale image. B, Color Doppler image.

Cardiac examination time was increased by 20% in the extended protocol group (Table 2). Repeat evaluation was recommended more than twice as often. The proportion of incomplete examinations was more than double at initial examination and at follow-up examination in the extended protocol group, with 26% of cardiac examinations incomplete at initial examination compared with 11% in the basic protocol group. After 2 examinations, 21% of examinations were incomplete in the extended protocol group compared with 7% in the basic protocol group (Table 2).

The views obtained in the basic and extended protocol groups in our cohort are shown in Figure 8. Figure 9 illustrates views on complete examinations. All complete examinations in the basic protocol group obtained the 4CV, LVOT, and RVOT; 3VT view was obtained in most examinations at our center, although not required. All complete examinations in the extended protocol group obtained the 4CV, LVOT, and RVOT views plus the 3VV, 3VT, AA, and SVC/IVC. The 3VV and 3VT views were least likely to be incomplete in both groups. Figure 10 illustrates that the views most often incomplete in the extended protocol group were the AA, SVC/IVC, and RVOT views, whereas the 4CV was most often incomplete in the basic protocol group.

Maternal BMI significantly affected examination completion rates, and the effect was more pronounced in the extended protocol group, with the largest effect seen at BMI of 40 kg/m^2 or more (Table 3).

The frequency of fetal echocardiogram recommendation was unchanged. The rate of potential abnormalities detected was not increased in the extended protocol group (Table 4). As discussed previously, these statistics were unchanged with removal of the low-risk cohort.

Table 5 describes the concerns identified in the cohort. Five concerns were identified among high-risk women under each protocol (basic and extended), and 2 concerns were identified among low-risk women under each protocol. One case of critical CHD (aortic stenosis with aortic coarctation [Shone complex]) was detected in the low-risk cohort in the extended protocol group (Table 5). This case was suspected based on a stenotic-appearing aortic valve in the LVOT view, and the patient was referred for fetal echocardiogram.

DISCUSSION

Detection rates for CHD in the United States remain low, at less than 50% even for major anomalies and for high-risk
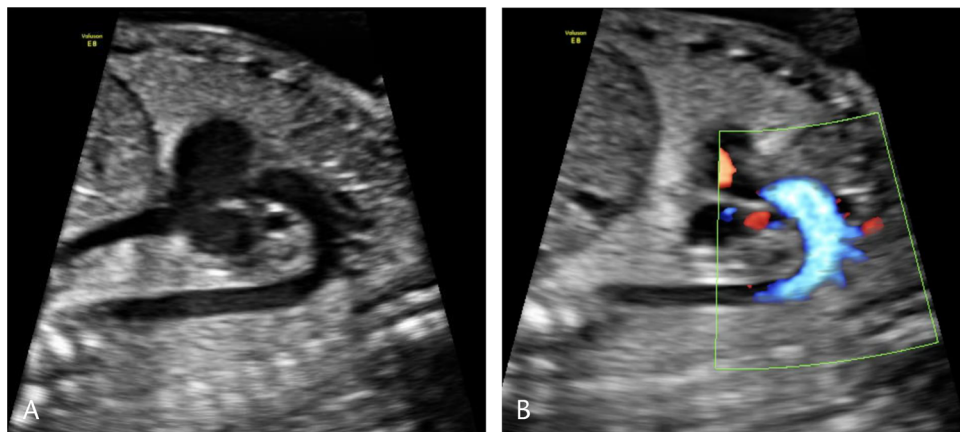
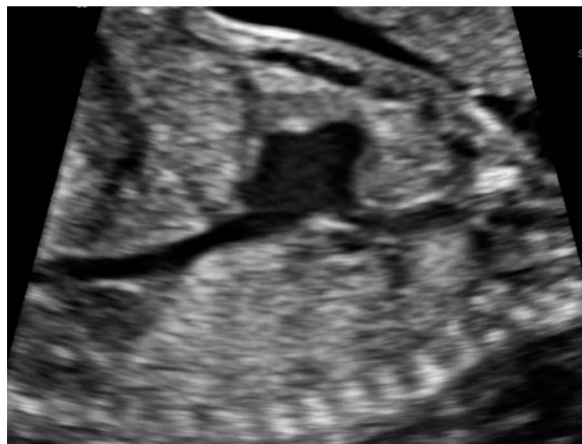FIGURE 6. Normal aortic arch at 23 weeks. A, Gray-scale image. B, Color Doppler image.

FIGURE 7. Normal SVC/IVC view at 20 weeks.

centers.[14,15] Prenatal diagnosis is valuable because it improves outcomes, especially for infants with severe cardiac anomalies.[3] Multiple strategies have been proposed and used to improve detection, including the use of additional views on screening examination, the use of 2-dimensional cine loops and sweeps, color and pulsed Doppler imaging, and 3-dimensional imaging.[14,16–18] In a 2016 editorial by Sklansky and DeVore,[14] the authors propose that, despite advances in cardiac imaging and the inclusion of additional views, detection of CHD remains low for 2 reasons: lack of focus on image quality and lack of familiarity with the appearance of abnormal cardiac anatomy. Our data suggest that the addition of the 3VV, 3VT, AA, and SVC/IVC views added time to each examination and increased the number of repeat examinations, without changing the frequency of referrals for echocardiogram or the identification of concerns. We agree with Drs Sklansky and DeVore that we must expand the focus of cardiac screening to emphasize high-quality image acquisition, without which we cannot reliably and thoroughly examine the fetal heart.

Over time, progressively more views have been added to the screening fetal cardiac examination. The addition of outflow tract views to the 4CV on screening examinations is necessary, as many major cardiac anomalies have a normal or near-normal 4CV.[3,15,19] The addition of the 3VV and/or 3VT view has also been proposed as a way to assess the great vessels, their size, and their anatomic relationship and to increase the prenatal detection of CHD.[20–22] The AA and SVC/IVC views are recent additions to the fetal screening examination.[13] Cine loops and color imaging of any views are not explicitly required.[12,13]

TABLE 1. Demographic Data

	Basic Protocol (n = 217)	Extended Protocol (n = 407)	P
Age, mean (SD), years	30.7 (5.8)	31.5 (5.1)	0.08
No high-risk indication, n (%)	58 (27%)	91 (22%)	0.2
BMI, mean (SD), kg/m^2	27.6 (5.9)	28.4 (7.6)	0.2
Prior abdominal surgery, n (%)	52 (24%)	121 (30%)	0.5
Gestational age at initial examination, weeks, mean (SD)	21 wk 5 d (5.5)	20 wk 6 d (4.6)	0.02

TABLE 2. Primary Outcomes

	Basic Protocol (n = 217)	Extended Protocol (n = 407)	P
Cardiac examination time, mean (SD), min	6.4 (3.5)	7.7 (4.2)	<0.05
Incomplete on initial examination	24/217 (11%)	107/407 (26%)	<0.05
Repeat evaluation recommended*	13 (6%)	52 (13%)	< 0.05
Complete on repeat examination†	8/12 (67%)	22/51 (43%)	0.1
Complete after 2 examinations	201/217 (93%)	322/407 (79%)	<0.05

*Not all women with an incomplete examination were recommended to have a repeat examination.

†Not all women who were recommended to have a repeat examination obtained one.

Our data show that cardiac examination time in the extended protocol group was increased by 20%, although 1.3 minutes may not be clinically significant. We also note that 3VV/3VT views were already being obtained on most examinations prior to the protocol change in our center. Thus, the AA and SVC/IVC views were the major contributors to increased examination time. The frequent acquisition of 3VV/3VT views prior to protocol change likely reduced the difference in examination time, and a larger time difference could have been demonstrated had the 3VV/3VT not been routinely obtained in both groups. The addition of 76811 extended cardiac views to the screening examination increased the incomplete cardiac examination rate to 26%, compared with 11% under the basic protocol. Most importantly, the rate of repeat examination recommendation more than doubled, from 6% to 13%, a substantial increase in health care dollars and patient inconvenience. After a second attempt, 21% of examinations in the extended protocol group remained incomplete, compared with 7% in the basic protocol group.

Waller et al[23] reported that repeat examination was recommended for 52% of incomplete examinations and that 72% of examinations were complete on second attempt. We note a similar repeat examination recommendation rate at 50% and 48% of basic and extended protocol incomplete examinations, respectively, and a similar completion rate on repeat examinations in the basic protocol of 67%. Completion rate on repeat examination in the extended protocol group was nonsignificantly reduced at 43%. Silvestri et al[24] reported an incomplete examination rate of 13.2% in a cohort of women undergoing a detailed 76811 compliant examination, similar to our completion rate under the basic protocol. The authors also report that 91.5% of women with an incomplete examination of a normal appearing fetus were recommended to have a repeat examination, and 92.8% of these women obtained the repeat examination. We note that their population was restricted to gestational ages of 17 to 21 weeks, whereas we included women at a gestational age of 18 weeks or greater. Our study population reflects the patient population at our center, which receives referrals at a range of gestational ages. Restricting analysis to a small gestational age window would not allow a complete picture of the way fetal cardiac screening is performed in our unit.

Increased examination time and increased repeat examination rates increase cost and anxiety to the patient and cost to
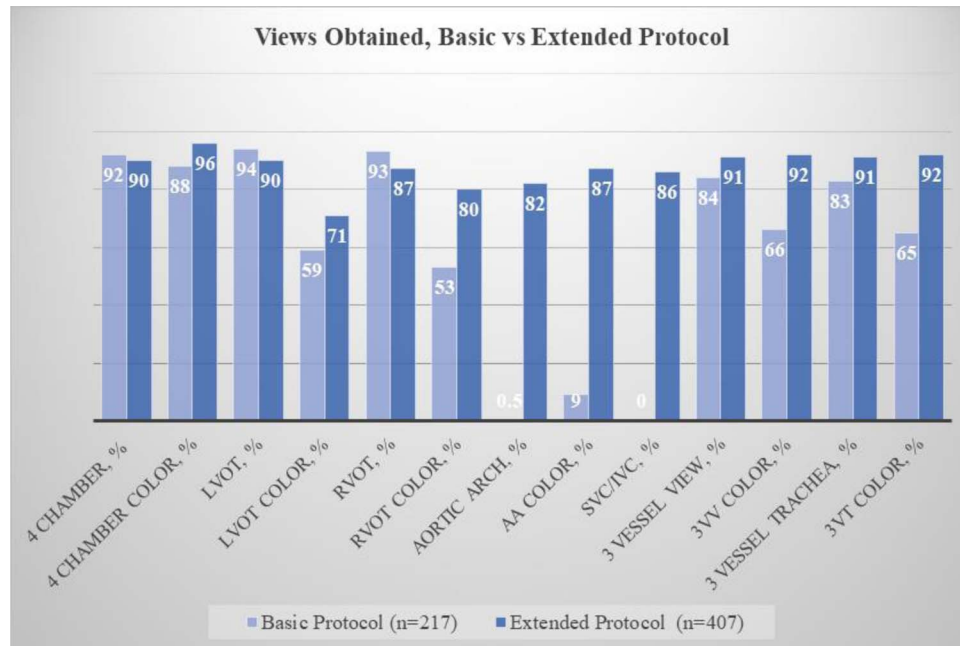
FIGURE 8. Views obtained in the basic protocol versus extended protocol.

the health care system. There is also personal cost to increased examination time and repeat examinations, including time required for the patients to make additional visits and ergonomic cost to sonographers of longer and increased examinations.[25]

Our data illustrate that the 4CV and outflow tract views (LVOT and RVOT) were obtained 87% to 94% of the time in all initial examinations regardless of protocol. The 3VV and 3VT views were obtained 84% to 91% of the time at initial examination. The AA and SVC/IVC were obtained 87% and 86% of the time in the extended protocol group. Previous data demonstrate that the addition of cine loops increases the number of structures cleared during an ultrasound examination[17,26]; thus, our protocol for all examinations included cine loops and color

Doppler imaging of the fetal heart. Color imaging was obtained in 53% to 88% of all views in the basic protocol and 71% to 96% of all views in the extended protocol, likely reflecting an increased emphasis on color views within our center.

The impact of obesity on ultrasound imaging during pregnancy cannot be overstated. Maternal obesity both increases the risk of congenital anomalies and decreases the likelihood of identifying them prenatally.[27] Multiple strategies have been proposed to combat this effect, including early anatomical surveys, the use of transvaginal imaging, the use of advanced imaging techniques, and later anatomical surveys in the obese gravida.[13,28,29] Completion rates for the midtrimester anatomic survey can be quite low in obese women at initial examination, with reported
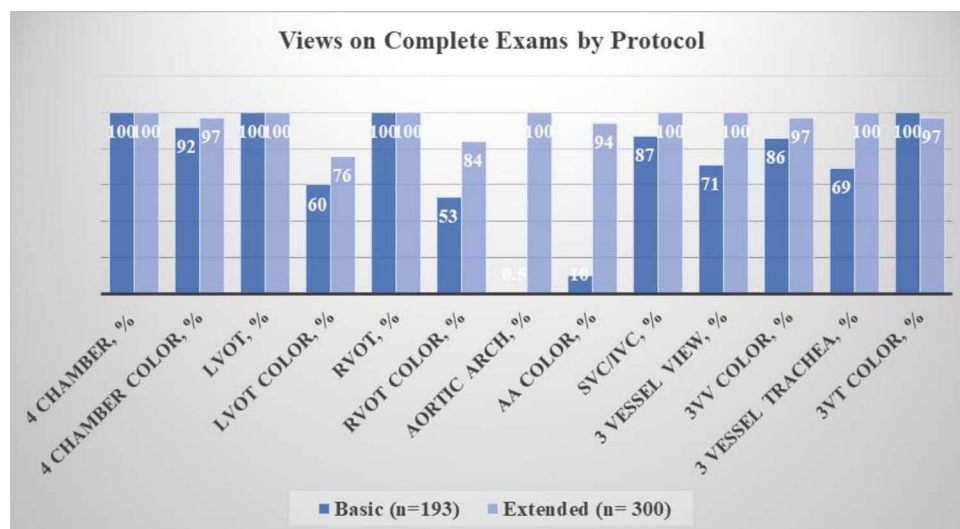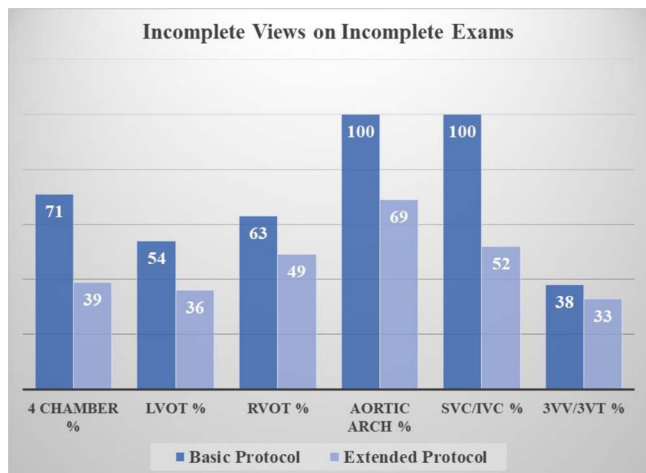

FIGURE 9. Views obtained on complete examinations in the basic protocol versus extended protocol.

FIGURE 10. Views called incomplete on incomplete examinations in basic protocol versus extended protocol.

rates of 30% to 50% in women with a BMI of 40 kg/m^2 or greater compared with 70% to 80% for a BMI of less than 30 kg/m^2.[27,29] Our completion rate at BMI 40 kg/m^2 or greater under the extended protocol is dramatically reduced at 14% compared with 85% in women with a BMI of less than 30 kg/m^2, although this may reflect small numbers in this group. We agree with Dashe et al[28,29] and Hendler et al[27,30] that counseling must reflect the fact that suboptimal visualization increases and detection of anomalies decreases in obese women.

In the study cohort, concerns for CHD were identified on the 4CV, RVOT, LVOT, 3VV, or 3VT views. No concerns were identified based solely on the AA or SVC/IVC views. In addition, we note that the cases of cardiac anomalies identified in the high-risk cohort include 2 ventricular septal defects (VSDs), one before and one after protocol change, and several concerns that resolved either antenatally or in the immediate postnatal period. In contrast, 1 abnormality of the great vessels (right aortic arch) and 1 case of severe CHD (aortic stenosis requiring fetal and neonatal balloon valvuloplasty) were identified in the low-risk cohort. The case of aortic stenosis was suspected on a follow-up examination recommended for limited heart views and was initially suspected in the LVOT view, whereas the right aortic arch was suspected on the 3VV/3VT view. We note that several of the concerns identified were suspected on 3VV (small pulmonary artery, enlarged aorta), and frequent acquisition of this view likely increases detection of concerns in the basic protocol group. Overall, 3 of 7 concerns could be identified on 3VV/3VT view in the basic protocol group and 1 of 7 concerns could be identified on 3VV/3VT view in the extended protocol group.

Rates of CHD are reported at up to 1%,[31] consistent with our cohort. Congenital heart disease identified included a bicuspid aortic valve, right aortic arch, 2 VSDs, and aortic stenosis, for 5 cases of 624 fetuses, or a rate of 0.8%. While the relatively small sample size, frequent use of 3VV/3VT in both groups, and lack of severe CHD cases limit conclusions about detection rate, the identification of concerns on the 4CV, LVOT, RVOT, 3VV, and 3VT views illustrates their utility in both low- and high-risk groups. Abnormalities in the 4CV, outflow tract, and 3VV/3VT views are clues to CHD and should prompt referral for fetal echocardiogram.[16,20,22] In contrast, abnormalities in the AA and SVC/IVC view alone are less common and more difficult to detect prenatally.[32–34] Signs may not be present until later in gestation, and fetal physiology can compensate for abnormalities in flow.[35,36] The incidence of concerns identified in the low- and high-risk groups and the incidence of true cardiac anomalies in each group were similar. Although our sample size is small and CHD is somewhat uncommon, our data suggest that a screening examination in any patient should include a 3VV and/or 3VT view in addition to the 4CV and outflow tracts. The risk of a cardiac anomaly in a low-risk patient, in our cohort, was not different than the risk of a cardiac anomaly in a high-risk patient without a prior cardiac anomaly identified. High-risk patients did not have enough of a risk of abnormalities on the SVC/IVC or AA views alone to justify the additional time and effort to obtain these views. Instead, our data suggest that focusing on high-quality images of the 4CV, outflow tracts, and 3VV/3VT views is more important than additional views, which did not add to our detection rate of concerning findings. Our data support the inclusion of 3VV/3VT views in every screening cardiac examination. We believe the focus should be on obtaining quality cardiac imaging with appropriate interpretation and referrals for fetal echocardiogram when indicated. Although we respect the recommendations of the major ultrasound and obstetrics societies, our study does not support addition of the aortic arch and bicaval views to the extended protocol examination.

Currently, screening for CHD is performed on 3 different levels per AIUM guidelines: (1) low-risk examination includes gray-scale still images of 4CV, RVOT, and LVOT (although at our institution we document all cardiac views using cine clips and include the 3VV/3VT views); (2) high-risk examination includes gray-scale still images of 4CV, RVOT, LVOT, 3VV, 3VT, bicaval, and aortic arch; and (3) fetal echocardiography includes gray-scale and color Doppler cine clips of 4CV, RVOT, LVOT, 3VV, 3VT, high and low short-axis views, aortic arch, ductal arch, and bicaval views with pulsed Doppler interrogation of cardiac valves, ductus venosus, umbilical cord (optional), and cardiac rhythm.[13,37]

TABLE 3. Completion Rates by BMI

	Basic Protocol (n = 217)	Extended Protocol (n = 407)	*P*
BMI <30 kg/m^2	142/152 (93%)	232/272 (85%)	<0.05
BMI 30–39 kg/m^2	45/55 (82%)	63/100 (63%)	<0.05
BMI ≥40 kg/m^2	6/10 (60%)	5/35 (14%)	<0.05

TABLE 4. Rate of Echocardiogram Recommendations and Concern for Cardiac Abnormalities

	Basic Protocol (n = 217)	Extended Protocol (n = 407)	*P*
Echocardiogram recommended, n (%)	10 (5%)	23 (6%)	0.6
Concern identified for cardiac abnormalities, n (%)	7 (3%)	7 (2%)	0.3

TABLE 5. Cardiac Concerns Identified in High- and Low-Risk Groups, With Follow-up and Outcomes

Basic Protocol (7 Cases)	Extended Protocol (7 Cases)
Concerns identified in high-risk patients (5 cases)	**Concerns identified in high-risk patients (5 cases)**
Pericardial effusion—resolved at follow-up	Muscular VSD—present postnatally; closed by 2 years of life
Small pulmonary artery—normal fetal echo	Dilated aorta—normal on fetal echo
Muscular VSD—not seen on fetal echo	Right, left disproportion with hypoplastic mitral valve; developed persistent pulmonary hypertension of the newborn; subsequently resolved and postnatal echo otherwise normal
Asymmetry of ventricles—normal on fetal echo	Tricuspid and mitral regurgitation—normal postnatal echo
Enlarged aorta—bicuspid aortic valve on postnatal echo	Echogenic tricuspid valve—normal on fetal and neonatal echo
Concerns identified in low-risk patients (2 cases)	**Concerns identified in low-risk patients (2 cases)**
Left axis deviation, right to left disproportion—multiple other anomalies and fetal 9q deletion on karyotype (amniocentesis)	Stenotic aortic valve—severe aortic stenosis with aortic coarctation (Shone complex); received fetal and neonatal aortic balloon valvuloplasty and coarct repair
Right aortic arch—confirmed on pre and post-natal echo; baby well without intervention at 5 mo of age	Muscular VSD—baby well at 2 years of life

This study reflects practice at a tertiary care academic referral center with a dedicated group of physicians and sonographers participating in regular advanced ultrasound training and internal case and quality review. As our referral center covers a wide regional area, some patients are referred for ultrasound alone and deliver outside our hospital system, limiting the ability to confirm all postnatal outcomes and anomalies. However, we have published outcome data from our center from 2006 to 2008 showing a detection rate of CHD of 78% using 4CV, LVOT, and RVOT views.[38] The lack of knowledge of our current CHD detection rate is a limitation of the current study.

In addition, the interpretation of when an image is adequate is subjective. Images were not reevaluated for adequacy by study personnel. The reading physician's interpretation was used. These limitations reflect the true state of practice at our center, and thus, our findings will be applicable to similar centers.

CONCLUSIONS

In our academic referral center, the addition of extended views required for 76811 billing led to increased examination time and repeat examination rate, increasing cost without a difference in the rate of referral for echocardiogram, or detection rate of concerning findings. Evaluation of the fetal heart should focus on image quality, which requires the time and expertise to integrate examination findings across cine loops and color imaging for the core high yield views (4CV, LVOT, RVOT, 3VV, and 3VT).

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