Fetal Medicine Foundation fetal and neonatal population weight charts

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Short title: Estimated fetal weight and birth-weight charts

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ABSTRACT

Objective: To develop fetal and neonatal population weight charts. The rationale for this objective is that while reference ranges of estimated fetal weight (EFW) are representative of the whole population, the traditional approach of deriving birth-weight (BW) charts is misleading because a high proportion of babies born preterm arises from pathological pregnancies. We propose that the reference population for BW charts, as in the case of EFW charts, should be all babies at a given gestational age including those still *in utero*.

Patients: Two sources of data were used for this study and in both the inclusion criteria were singleton pregnancy, dating by fetal crown-rump length at 11+0 to 13+6 weeks' gestation, ultrasonographic measurements of fetal head circumference (HC), abdominal circumference (AC) and femur length (FL), and livebirth of phenotypically normal neonate. Dataset 1, comprised a sample of 5,163 paired measurements of EFW and BW; the ultrasound scans were carried out at 22-43 weeks' gestation and birth occurred within 2 days of the ultrasound examination. The EFW was derived from the measurements of HC, AC and FL using the formula reported by Hadlock *et al.* in 1985. Dataset 2, comprised a sample of 95,579 pregnancies with EFW obtained by routine ultrasonographic fetal biometry at 20+0 to 23+6 weeks' gestation (n=45,034), or at 31+0 to 33+6 weeks (n=19,224) or at 35+0 to 36+6 weeks (n=31,321); for the purpose of this study we included data for only one of the three visits.

Methods: In the development of reference ranges of EFW and BW with gestational age the following assumptions were made: first, the EFW and BW have a common median, dependent on gestational age and second, deviations from the median occur in both EFW and BW and these deviations are correlated with different levels of spread for EFW and BW, dependent on gestational age. We adopted a Bayesian approach to inference combining information from the two datasets using Markov Chain Monte–Carlo sampling (MCMC). The fitted model assumed that the mean log transformed measurements of EFW and BW are related to gestational age according to a cubic equation and that deviations about the mean follow a bivariate Gaussian distribution.

Results: In the case of EFW in dataset 2 there was a good distribution of values <3rd, <5th, <10th, >90th, >95th and >97th percentiles of the reference range of EFW with gestational age throughout the gestational age range of 20^{+0}- 36^{+6} weeks. In the case of BW there was a good distribution of values only for the cases born at >39 weeks' gestation. For preterm births, particularly at 27-36 weeks, the BW was below the 3rd, 5th and 10th percentiles in a very high proportion of cases and this was particularly marked for cases of iatrogenic birth. The incidence of SGA fetuses and neonates in the respective EFW and BW charts was higher in women of Black than White racial origin.

Conclusion: We established a BW chart for the population of all babies at a given gestational age, including those still in *utero,* which overcomes the problem of underestimation of growth restriction in preterm births. The BW and EFW charts have a common median but they differ in the levels of spread from the median.

INTRODUCTION

There is an apparent contradiction in the relation between the ultrasonographic estimation of fetal weight (EFW) and birth weight (BW). Although the EFW recorded within a few days of birth correlates strongly with BW and for a given gestational age they have essentially the same median,[1] in reported reference ranges the median BW with gestational age for babies born preterm is substantially lower than that of the EFW.[2-5] This difference is likely to be the consequence of pathological fetal growth in a high proportion of preterm births. Reference ranges of EFW are representative of the whole population, whereas in the construction of reference ranges of BW, particularly for gestational ages at <37 weeks, there is overrepresentation of pathological pregnancies. One third of preterm births are iatrogenic mainly for hypertensive disorders and / or suspected fetal growth restriction; there is also evidence that in a substantial proportion of spontaneous preterm births there is impaired placentation.[6-10]

In this study we propose that the reference population for BW charts, as in the case of EFW charts, should be all babies at a given gestational age including those still *in utero*. These charts assume that, first, for a given gestational age the median BW is the same as the median EFW in the reference population and second, deviations from the median occur in both BW and EFW and these deviations follow a bivariate Gaussian distribution with different levels of spread for BW and EFW, dependent on gestational age. These assumptions enable data on EFW, from routine scans at early gestations to be combined with BW at term to produce reference charts for BW and EFW for gestational ages from 20^{+0} to 41^{+6} weeks.

METHODS

Study population

Two sources of data were used for this study and in both the inclusion criteria were: singleton pregnancy, dating by fetal crown-rump length at 11^{+0} to 13^{+6} weeks' gestation, ultrasonographic measurements of fetal head circumference (HC), abdominal circumference (AC) and femur length (FL) and livebirth of phenotypically normal neonate. The pregnancies were examined at King's College Hospital, London and Medway Maritime Hospital, Kent, UK (between January 2006 and December 2017). The ultrasound scans were carried out by sonographers that had received the Fetal Medicine Foundation (FMF) Certificate of competence in ultrasound scanning.

Dataset 1, comprised a sample of 5,163 paired measurements of EFW and BW; the ultrasound scans were carried out at 22-43 weeks' gestation and birth occurred within 2 days of the ultrasound examination.[1] This dataset, in which pathological pregnancies were inevitably overrepresented, was used to examine the relationship between EFW and BW; the reference ranges were established from Dataset 2. The EFW was derived from the measurements of HC, AC and FL using the formula reported by Hadlock *et al.*[11] We previously conducted a systematic review of the literature to identify all models for EFW and found that the formula of Hadlock *et al.*[11] was the most accurate among 70 published models for prediction of BW with the lowest Euclidean distance and highest proportion of pregnancies with an absolute mean error of $\leq$10.[1]

Dataset 2, comprised a sample of 95,579 pregnancies (not included in dataset 1) with EFW obtained by routine ultrasonographic fetal biometry at 20+0 to 23+6 weeks' gestation (n=45,034), or at 31+0 to 33+6 weeks (n=19,224) or at 35+0 to 36+6 weeks (n=31,321). In the participating hospitals all women with singleton pregnancies are offered routine ultrasound examinations at 11^{+0} to 13^{+6} and at 20^{+0} to 23^{+6} weeks' gestation. During a period (2011 to 2014) an additional scan was offered at 31^{+0} to 33^{+6} weeks, but subsequently (2014 to 2017) this was changed to 35^{+0} to 36^{+6} weeks. For the purpose of this study we included data for only one of the second / or third trimester visits; we used all data obtained at 31^{+0} to 33^{+6} or 35^{+0} to 36^{+6} weeks and used the data for the visit at 20^{+0} to 23^{+6} weeks only from pregnancies that did not have a third trimester scan. In the selection of patients care was taken to include routine scans and not follow-up scans for maternal medical conditions or a suspected problem in fetal growth. Since the objective of the study was to establish reference ranges, rather than normal ranges, we included all pregnancies undergoing these routine ultrasound examinations.

Statistical analysis

Measurements of EFW and BW were log transformed to make the deviations from the median close to Gaussian and the variation about the median more stable across the range of gestational ages. We adopted a Bayesian approach to inference combining information from data sets 1 and 2 using Markov Chain Monte–Carlo sampling (MCMC). The fitted model assumes that the mean log transformed measurements of EFW and BW are related to gestational age according to a cubic equation and that deviations about the mean follow a bivariate Gaussian distribution. Gross outliers were identified from an initial model and observations with standardized residuals beyond ±3.89 (the 0.00005 percentile of the Gaussian distribution) were excluded from the final model. A range of model diagnostics was produced to assess the goodness of fit of the model. This included summary statistics and Gaussian probability plots of z-scores for data on EFW and BW. Non-parametric quantile regression was used for direct estimation of percentiles of the EFW and BW data for comparison with the parametric model. Details of the analysis and model diagnostics are given in Appendix 1.

The statistical software package R was used for data analyses.[12] The R packages mvtnorm[13] and quantreg[14] were used for multivariate Gaussian statistics and quantile regression.

Results

Pregnancy characteristics of the two datasets are summarized in supplementary Tables S1 and S2. The association between EFW and BW in 5,163 pregnancies in dataset 1, where birth occurred within 2 days of the ultrasound examination, is shown in Figure 1. For a given gestational age the median EFW is essentially the same as that for BW. Further evidence for the assumption of equivalence in means of EFW and BW is provided in Appendix 1.

The median, 3rd, 10th, 90th and 97th percentiles of EFW and BW with gestational age are shown in Figure 2 and median, 3rd, 5th 10th, 25th, 75th, 90th, 95th and 97th percentiles of EFW and BW at mid gestational age for each week between 20 and 42 weeks are shown in Table 1. The standard deviation and percentiles of EFW and BW for each gestational age day between 20 and 42 weeks are shown in Table S3.

The distribution of EFW with gestational age of our chart is compared to that of the World Health Organization (WHO)[5] and Intergrowth-21st[4] in Figure 3 and Table S4. The median and 10th percentiles of the WHO chart[5] and more so those of the Intergrowth-21st chart[4] are substantially lower than the respective ones in the FMF chart.

The percentage of cases in dataset 2 with EFW and BW <3rd, <5th <10th, >90th, >95th and >97th percentiles of the appropriate preference range with gestational age are shown in Table S5. In general, the distribution of values for EFW is well balanced throughout the gestational age range of 20^{+0} - 36^{+6} weeks. In the case of BW there is a good distribution of values only for the cases born at >39 weeks' gestation. For preterm births the BW is below the 3rd, 5th and 10th percentiles in a very high proportion of cases (Figure 4, Table S6). This is particularly marked for cases of iatrogenic birth (40.3%, 45.1% and 52.5%, respectively), which is not surprising because in 1,200 (67.0%) of the 1,790 cases the indication for delivery was hypertensive disease and / or fetal growth restriction. However, a high proportion of small for gestational age (SGA) neonates was also observed in spontaneous preterm births; the proportion of spontaneous preterm births with birthweight below the 3rd, 5th and 10th percentiles was 8.6%, 12.4% and 19.8%, respectively (Table S6).

The percentage of pregnancies in women of White and Black racial origin in dataset 2 with EFW and BW <3rd, <5th and <10th percentiles of the appropriate reference range with gestational age are shown in Table S7 and the percentage of cases with EFW and BW <10th percentiles are illustrated in Figure 5. The data demonstrate that the incidence of SGA fetuses and neonates in the respective EFW and BW charts is higher in women of Black than White racial origin.

Discussion

Principal findings of this study

This study has established reference ranges with gestational age for BW and EFW. The two charts have a common median but they differ in the levels of spread from the median. The BW charts rely on the principle that at a given gestational age, especially at <37 weeks, the reference population should not be only those babies that are born, because preterm births are inherently pathological, but all babies including those still *in utero*.

The study has demonstrated that a very high proportion of preterm births are SGA; this should not be surprising because in many such cases there is iatrogenic birth for hypertensive disease and / or fetal growth restriction. A high proportion of SGA neonates is also observed in spontaneous preterm births providing further support to the results of histological and uterine artery Doppler findings that in many such births there is impaired placentation.[5-10] Consequently, to varying degrees, all preterm births arise from pathological pregnancies and it is misleading to use data from such pregnancies to establish reference ranges of BW with gestational age.

In our heterogeneous unselected population arising from two maternity hospitals in England, about 20% of the women were of Black racial origin and in such women the incidence of SGA fetuses and neonates was higher than in White women. This finding is compatible with the results of a previous study which reported that fetal growth is affected by several maternal characteristics; BW increased with maternal weight, height and parity and after adjustment for these variables BW was lower in Black than in White women.[15] It could therefore be assumed that it is physiological for Black women to produce smaller babies than White women and provide different reference ranges for these racial groups.[16] The alternative view is that in Black women living in England the delivery of smaller babies is a consequence of pathological influences that would be masked by customized birthweight percentiles. We have previously reported that in Black women, after adjustment for other demographic and pregnancy characteristics, there is increased risk for several adverse pregnancy outcomes, including miscarriage, stillbirth, preeclampsia, fetal growth restriction and both iatrogenic and spontaneous preterm birth; it is uncertain whether such increased risks are the consequence of genetic predisposition, socioeconomic deprivation or both.[17] We have also shown that BW for gestational age is reduced in antepartum stillbirths and there is no significant difference in the proportion of antepartum stillbirths that are SGA when BW is corrected for maternal characteristics.[15]

Strengths and limitations of the study

The main strength of our study is the production of BW reference charts for the population of all babies at a specific gestational age including those still *in utero*. This avoids bias and underestimation of SGA in the assessment of BW in babies born preterm. Additional strengths include large study population of women undergoing routine ultrasound examination in pregnancy for database 2 and use of their data only once to avoid the potential correlation of measurements from different visits, close proximity of the ultrasound examination to birth for database 1, pregnancy dating based on fetal crown-rump length, trained sonographers that carried out fetal biometry according to a standardized protocol and use of a widely used model for calculation of EFW [11] which has been shown to be the most accurate one among 70 previously reported models.[1] In the establishment of reference ranges we included all pregnancies undergoing routine ultrasound examination and did not attempt to select only uncomplicated pregnancies in women thought to be healthy and well-nourished.

In our study we assumed that, for a given gestational age, EFW and BW have the same median. This was based on the findings from dataset 1, but was not possible to investigate further for the whole population. Another limitation is the extent of extrapolation and interpolation resulting for use of data on EFW and BW. We wanted to include data on EFW arising from routine screening of the whole population and this inevitably restricted the data to the three narrow gestational age ranges of 20^{+0} to 23^{+6}, 31^{+0} to 33^{+6} and 35^{+0} to 36^{+6} weeks. Similarly, we restricted data on BW to pregnancies delivering at term to avoid bias from inclusion of preterm births, many of which arise from pathological pregnancies. Despite the extensive extrapolation and interpolation of data the model diagnostics demonstrated a satisfactory fit of the model.

Comparison with previous studies

Solomon *et al*, used the Hadlock formula[11] to construct EFW charts from biometric data obtained during routine ultrasound examination at 20–36 weeks' gestation in 18,959 normal fetuses.[3] The authors compared the EFW to BW charts obtained during the same study period and in the same single health authority and noted that for preterm births the EFW was substantially higher than BW; they recommended that the EFW of preterm fetuses should not be compared with the distribution of BW, because fetal growth restriction is over-represented in preterm births, but rather they should be compared to EFW charts. In our study, we have taken this observation further to highlight that there is an inherent problem in the traditional construction of BW charts, especially for preterm births, and they should be revised based on data from all babies at a given gestational age, including those still *in utero*.

Marsal *et al,* recognized that BW charts do not represent the intrauterine population and proposed that it would be preferable to use EFW charts to assess the growth of both fetuses and neonates.[2] They performed a longitudinal study of ultrasonographic fetal biometry at 10-41 weeks' gestation in 86 uncomplicated pregnancies that delivered at term; they then combined the data from 759 EFW's and 86 BW's to derive an intrauterine growth chart using a fourth degree polynomial equation. We agree with Marsal *et al,*[2] on the need to revise BW charts and have demonstrated that EFW and BW charts have a common median but they differ in the levels of spread from the median.

Two international multicentre studies have recently reported the construction of EFW for gestational age charts.[4,5] In the Intergrowth-21st project, data were derived from 2,404 live babies without congenital abnormality, who were born within 14 days of an ultrasound scan; women were recruited from urban areas in several countries (Brazil, China, England, India, Italy, Kenya, Oman, Pakistan, South Africa, Thailand and USA) and had serial ultrasound scans and fetal biometry throughout pregnancy.[4] Two cohorts of women were examined; one was unselected and the other was selected to include healthy, well-nourished, pregnant women who were at low risk of adverse maternal and perinatal outcomes. The authors reported that the data from different centres were similar and they therefore pooled all data and used fractional polynomial models to construct an international optimal fetal growth chart that would be appropriate for healthy pregnancies in all countries of the world.[4]

In the WHO study, data were derived from 1,387 healthy women with low-risk pregnancies and unconstrained nutritional and social background who had serial ultrasound scans throughout pregnancy; women were recruited from ten countries (Argentina, Brazil, Democratic Republic of the Congo, Denmark, Egypt, France, Germany, India, Norway and Thailand) and a total of 7,924 sets of ultrasound measurements were analyzed by quantile regression to establish longitudinal reference intervals for EFW.[5] The authors reported that there were significant differences in fetal growth between countries.

In our study, by comparison with the Intergrowth-21st and WHO studies, the population was unselected and considerably larger, the data were derived from two centres in the same country and the scans were carried out by sonographers with extensive training in ultrasound examination in pregnancy. Our approach, like the one for Intergrowth-21st, used a parametric model. This differs from the WHO approach which used non-parametric quantile regression. A benefit of the parametric models is that they can easily be used to obtain z scores and percentiles for individual measurements. A drawback is the imposition of a specific parametric relationship. We used a cubic polynomial to represent the relationship between median level of log transformed weight assuming the same median for both EFW and BW. Our model assumed that deviations around the median for BW and EFW followed a bivariate Gaussian distribution.

The 10th percentile of our EFW chart was considerably higher than that of the Intergrowth-21st and WHO.[4,5] For example, at 36 weeks' gestation the 10th percentile according to our chart is 2,531 g, whereas the respective values in the WHO and Intergrowth-21st charts are 2,352 g and 2,144 g. Such differences are likely to be the consequence of underlying differences in the study populations and demonstrate that the desire for a single international standard for all countries is not appropriate; a single standard would underestimate growth restriction in countries with normal big babies, such as Norway, and overestimate growth restriction in countries with normal small babies, such as India.

Conclusions

This study has highlighted the necessity that the construction of BW charts should be based on babies from all pregnancies at a given gestational age including those still *in utero.* Within a given country there are variations in BW that depend on maternal characteristics, such as racial origin, but adjustment for such characteristics may be inappropriate because such adjustments could result in underestimation of the increased perinatal risk of a disadvantaged group. The value of adjustment for maternal weight, height and parity remains controversial.

If our charts are to be used in different countries it would be necessary to ensure that the distribution of values is appropriate, otherwise adjustments would be necessary to either tailor the charts for a specific setting or change the cut-offs for defining small or large for gestational age. In the latter case, the charts could be considered as a benchmark rather than a reference chart.

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Figure legends

Figure 1. Association between estimated fetal weight (EFW), derived from the model of Hadlock *et al.,* using the measurements of head circumference, abdominal circumference and femur length,[9] and birth weight (BW) in Dataset 1. The regression line is shown in blue and the line EFW = BW is shown in red.

Figure 2. Median for both estimated fetal weight (EFW) and birth weight (BW) with gestational age (black line). The solid lines (blue for EFW and red for BW) represent the 10th and 90th percentiles and the interrupted lines represent the 3rd and 97th percentiles.

Figure 3. Comparison of the 50th (solid lines) and 10th (interrupted lines) percentiles of estimated fetal weight with gestational age between the WHO (green),[4] INTERGROWTH-21st (red) [3] and FMF (blue) charts.

Figure 4. Percentage of cases in Dataset 2 with birth weight below the 3rd (white histogram), 5th (grey histogram) and 10th (black histogram) percentiles of the reference range of birth weight with gestational age.

Figure 5. Percentage of pregnancies of White women (white histogram) and Black women (black histogram) in Dataset 2 with estimated fetal weight (left) and birth weight (right) below the 10th percentile of the appropriate reference range with gestational age.

Table 1. Median, 3rd, 5th 10th, 25th, 75th, 90th, 95th and 97th percentiles of estimated fetal weight (EFW) and birth weight (BW) at mid gestation.

Gestational age		Percentile																
		3rd		5th		10th		25th		Median	75th		90th		95th		97th	
Weeks	Days	EFW	BW	EFW	BW	EFW	BW	EFW	BW		EFW	BW	EFW	BW	EFW	BW	EFW	BW
20	143	300	283	306	290	314	301	329	322	346	364	372	381	398	306	290	399	424
21	150	358	337	364	345	375	359	392	384	413	435	445	455	475	364	345	477	507
22	157	424	399	432	410	444	427	466	456	491	517	528	542	564	432	410	567	603
23	164	501	472	510	484	525	504	550	538	580	611	624	641	668	510	484	671	713
24	171	588	554	599	568	616	592	646	633	682	719	734	754	785	599	568	791	839
25	178	686	646	699	664	719	691	755	739	797	841	859	883	919	699	664	926	982
26	185	796	750	811	771	835	803	877	859	926	978	999	1027	1069	811	771	1078	1143
27	192	918	866	936	889	964	926	1013	992	1070	1131	1154	1188	1236	936	889	1248	1322
28	199	1052	993	1072	1020	1105	1062	1162	1138	1228	1299	1326	1365	1420	1072	1020	1435	1520
29	206	1197	1130	1221	1161	1258	1210	1324	1297	1400	1481	1512	1558	1620	1221	1161	1638	1735
30	213	1353	1278	1380	1313	1423	1369	1498	1468	1586	1678	1713	1767	1836	1380	1313	1858	1967
31	220	1518	1435	1549	1475	1598	1538	1683	1649	1782	1888	1926	1988	2066	1549	1475	2092	2213
32	227	1691	1599	1725	1643	1780	1714	1876	1839	1988	2107	2150	2221	2307	1725	1643	2338	2472
33	234	1868	1768	1907	1817	1968	1895	2075	2034	2201	2334	2381	2461	2555	1907	1817	2593	2740
34	241	2048	1938	2091	1993	2159	2079	2277	2233	2416	2564	2615	2705	2808	2091	1993	2851	3012
35	248	2226	2108	2273	2167	2347	2262	2478	2430	2631	2793	2849	2948	3060	2273	2167	3110	3284
36	255	2398	2272	2449	2336	2531	2439	2672	2621	2839	3017	3076	3186	3306	2449	2336	3362	3549
37	262	2561	2427	2616	2496	2704	2607	2857	2802	3037	3229	3292	3412	3539	2616	2496	3602	3801
38	269	2709	2568	2768	2642	2862	2760	3026	2968	3219	3424	3490	3620	3754	2768	2642	3824	4034
39	276	2839	2692	2901	2770	3001	2894	3174	3114	3379	3596	3665	3804	3944	2901	2770	4021	4239
40	283	2945	2795	3011	2876	3115	3006	3297	3236	3512	3740	3811	3959	4103	3011	2876	4187	4412
41	290	3025	2872	3094	2956	3201	3090	3390	3328	3613	3851	3923	4078	4225	3094	2956	4315	4546

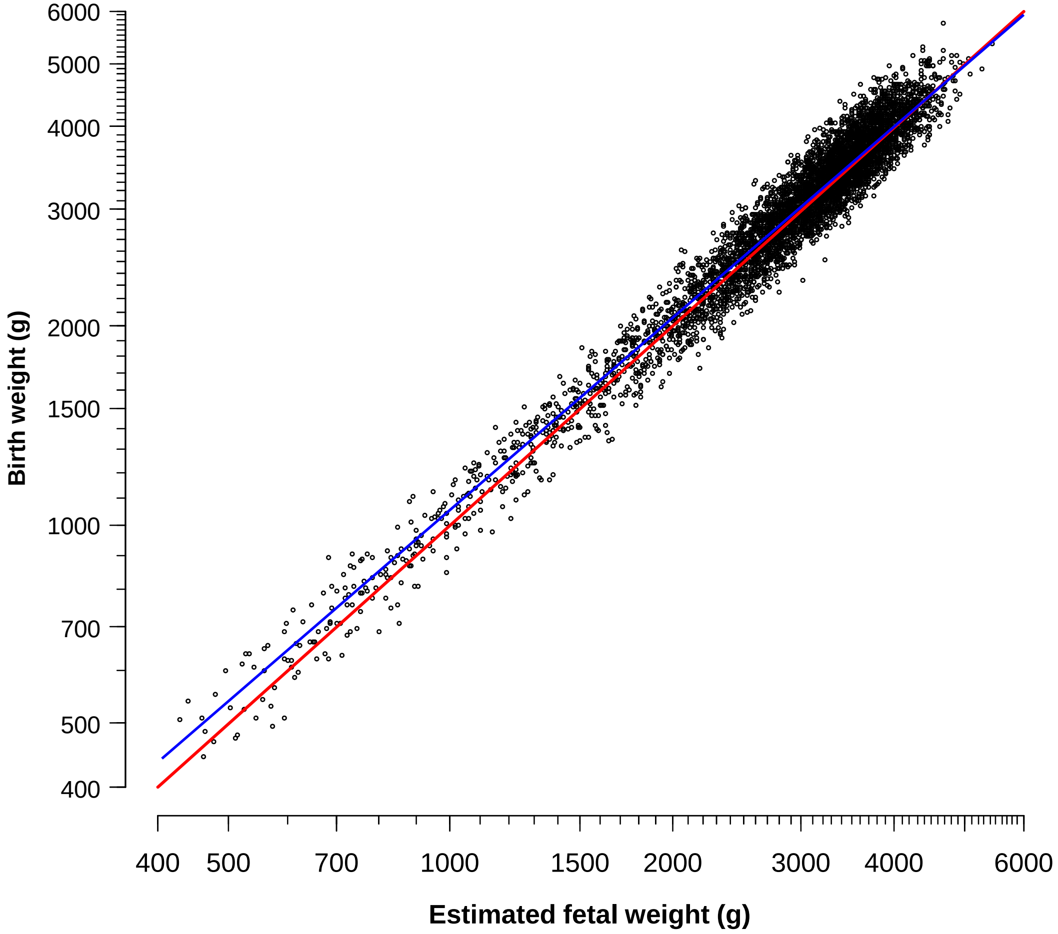
6000
5000
4000
3000
2000
1500
1000
700
500
400
Birth weight (g)
400
500
700
1000
1500
2000
3000
4000
6000
Estimated fetal weight (g)

Figure 1

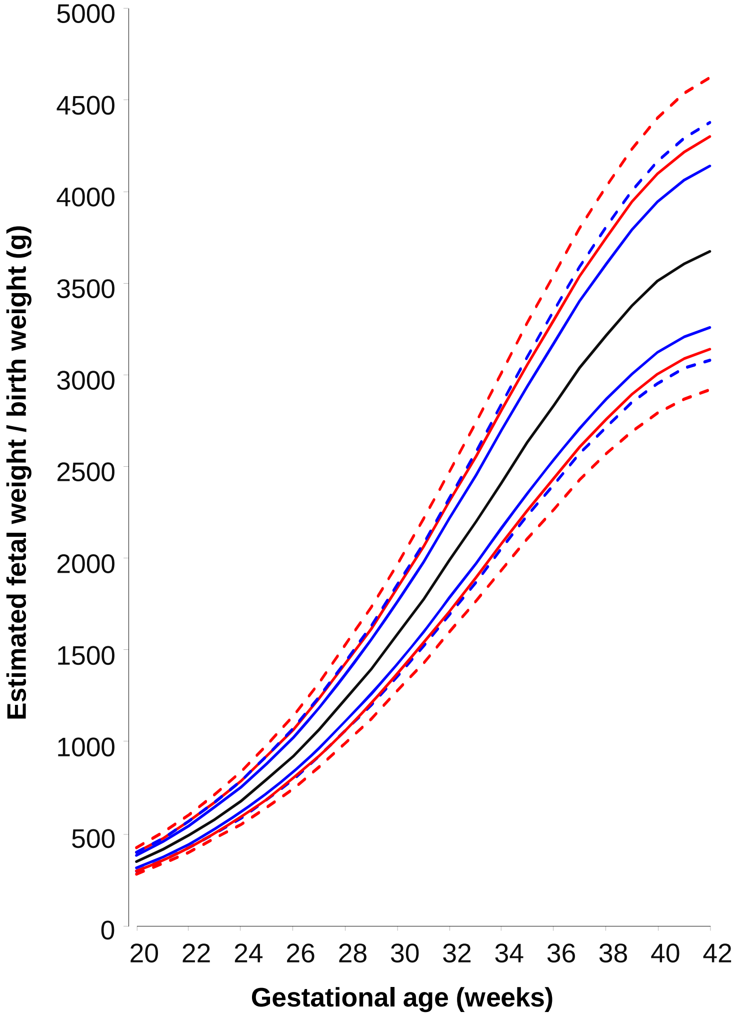
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
20
22
24
26
28
30
32
34
36
38
40
42
Estimated fetal weight / birth weight (g)
Gestational age (weeks)

Figure 2

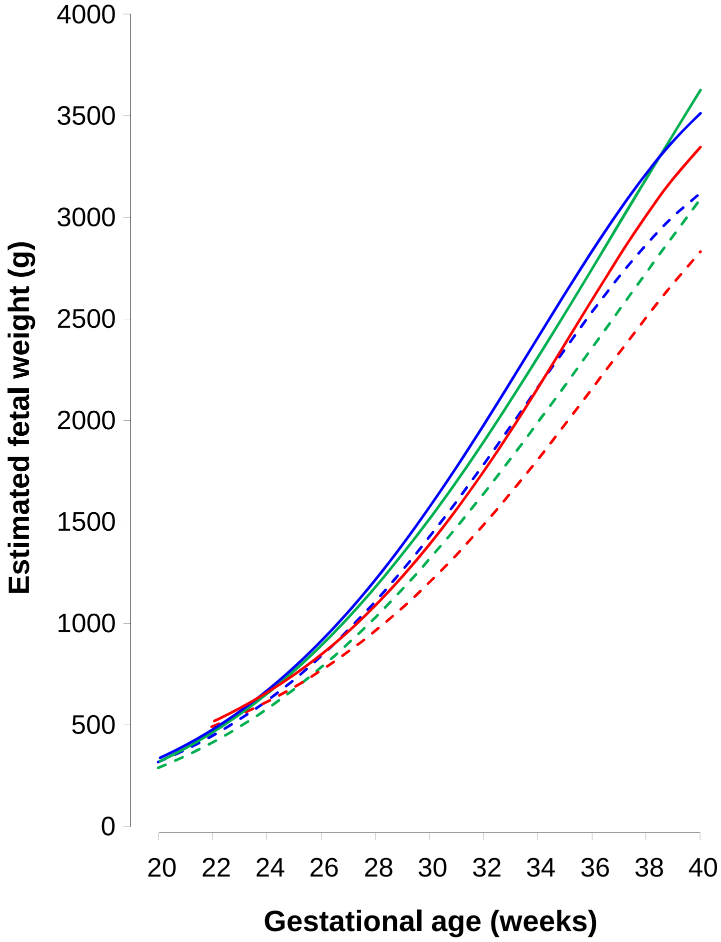
Estimated fetal weight (g)
4000
3500
3000
2500
2000
1500
1000
500
0
20
22
24
26
28
30
32
34
36
38
40
Gestational age (weeks)

Figure 3

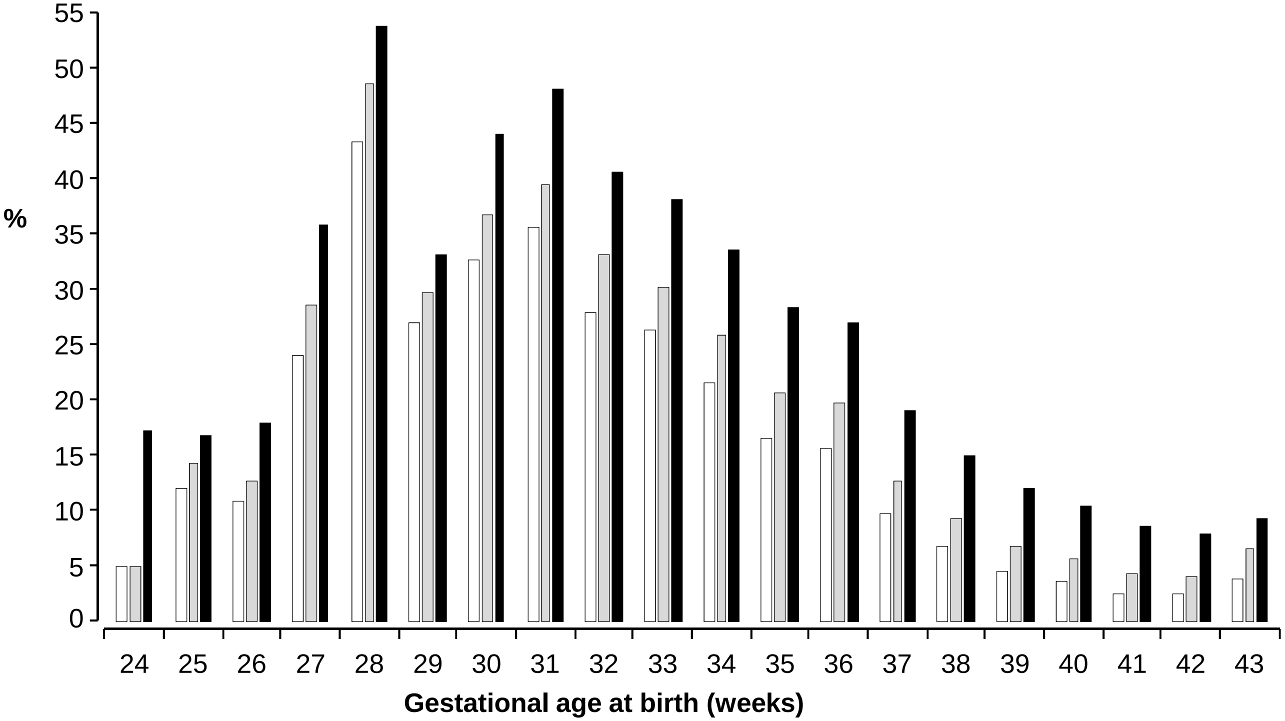
55
50
45
40
35
30
25
20
15
10
5
0
%
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
Gestational age at birth (weeks)

Figure 4

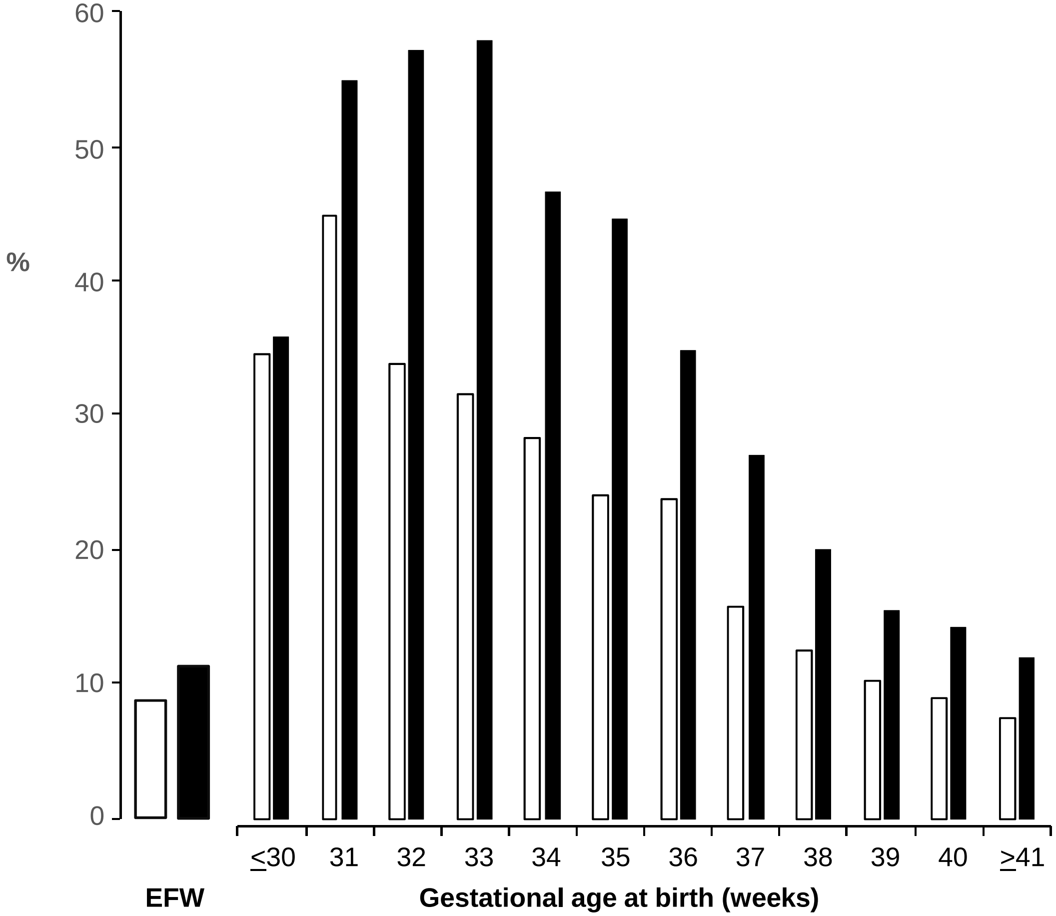
%
60
50
40
30
20
10
0
≤30
31
32
33
34
35
36
37
38
39
40
≥41
EFW
Gestational age at birth (weeks)

Figure 5