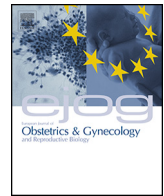




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Development of a birthweight standard and comparison with currently used standards. What is a 10th centile?

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ABSTRACT

Introduction: Fetal growth charts are often used in clinical practice. It is important to understand the usefulness and the pitfalls associated with these tools. Without validation, it is difficult to ascertain if the cutoffs we intend are the ones we actually select. We developed a national standard for birthweight (BW) and compared it with other published reference values.

Study design: Multicenter retrospective study. We collected data on live births, including first trimester ultrasound and pathology, from 23 to 42 weeks' gestational age (GA). We used a variation of the lambda (λ), mu (μ), and sigma (σ) method (LMS) to construct and smooth predicted centiles. GA data was plotted and modeled in days from 24 to 42 weeks. Resulting centiles were validated and compared with other published and widely used reference values. Data from both BW and estimated fetal weight was used to validate the model.

Results: Data on 661,338 births were collected from 22 institutions, including 71,515 cases with first trimester ultrasound. We excluded preterm cesarean section from analysis, because of a significant bias (up to 18%) on BW and used exclusively first trimester ultrasound dates from 34 to 42 weeks. The standard compares favorably with tables currently in use, both ultrasound and birthweight based.

Conclusion: The use of first trimester ultrasound limits variability by minimizing some random error sources, such as data introduction and GA errors, while allowing better precision (GA in days). This results in a narrower range in the extreme centiles than other charts. Validation with estimates of fetal weight are sound in second and early third trimester fetuses, because that will be a "real world" usage of this standard. While there are similarities between our series and some international/foreign growth charts, other are unfit to characterize our population. This reinforces the need for validation of standards, and sound methodological practices when doing so.

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Introduction

Obstetricians and neonatologists worldwide are familiar with the concept of fetal growth charts, arguably introduced by Lubchenco et al. in 1963 [1], in which birthweight is plotted as a function of gestational age (GA). As growth centiles correlate with fetal and neonatal outcomes, these are often used to produce clinical judgements. While several limitations and pitfalls are apparent, these are readily available tools, easy to understand and

widely adopted [2,3]. Given the large number of such charts published over the years, it is up to the clinician to choose one to which compare its population of fetuses/newborns. Such choice and its implications are not always well understood [4] and even professional societies sometimes do not agree on recommendations based on available evidence [5].

Whatever the tool, validation is of paramount importance, to ensure that, when the clinician selects the 10th centile, he is indeed referring to 10% of his intended population (e.g., a healthy local woman). We aim to describe how a population standard relates to others, and if differences are clinically significant, given the regional, ethnical and geographical differences previously identified [6–8]. We describe a birthweight (BW) standard for Portugal,

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from 24 to 42 weeks and compare it with other commonly used charts.

Methods

Participants

Singleton neonates from gestational age (GA) 168–300 days (23–42 completed weeks), live born between January 2004 and June 2014. Mothers with medical pathology were excluded from analysis (hypertensive diseases and diabetes, gestational or otherwise; autoimmune diseases; epilepsy; chronic medications). Newborn malformations, including chromosomal abnormalities, and hemolytic diseases were also excluded.

Study design

Cross sectional study. We identified and sought institutional authorizations for data retrieval regarding births in state financed maternity hospitals with over 1500 births per year.

Data collection

Computerized records of births and first trimester ultrasound were collected. Standardized record search strategies were developed in the main Portuguese Electronic Patient Record (SONHO, currently maintained by state owned Serviços Partilhados do Ministério da Saúde, Portugal) and the fetal ultrasound software Astraia (Astraia software GmbH, Munich, Germany). Databases were joined by using unique anonymized identifiers: institutional

episode, patient record for ultrasound data. Additional validations were: dates of ultrasound and birth, calculated (ultrasound) and recorded GA. Ultrasound based estimates of fetal weight (EFW) were available in 17 institutions and used for validation purposes. A validation sample of BW from June 2014 to August 2016 was additionally collected from one of the participant hospitals.

Variables description

We collected institution name, mother's age, parity, medical and pregnancy related conditions, last menstrual period (LMP), date and Crown Rump Length (CRL) of first trimester ultrasound, EFW(s), newborn diagnosis, birth date, newborn sex, recorded gestational age, birthweight (BW), and type of delivery. Birth and ultrasound queries included, respectively, episode and patient diagnosis. We calculated GA with Hadlock's CRL formula [9]. Validation data for EFW in low GA fetuses was based in Hadlock's 4 parameter formula [10].

Statistical analysis

GA was calculated in days by ultrasound (CRL up to 85 mm). Given the scarcity of premature births, we decided to use the full dataset, regardless of ultrasound dating, in newborns with GA <34 weeks, while exclusively using complete (with CRL) data from 34 weeks (238 days) onward.

An obstetrician (RS) scanned the birthweight dataset for probable data errors, with the aid of the Tukey method for outlier identification [11]. We explored the previously reported associations of cesarean delivery with observed birthweight [12], as well

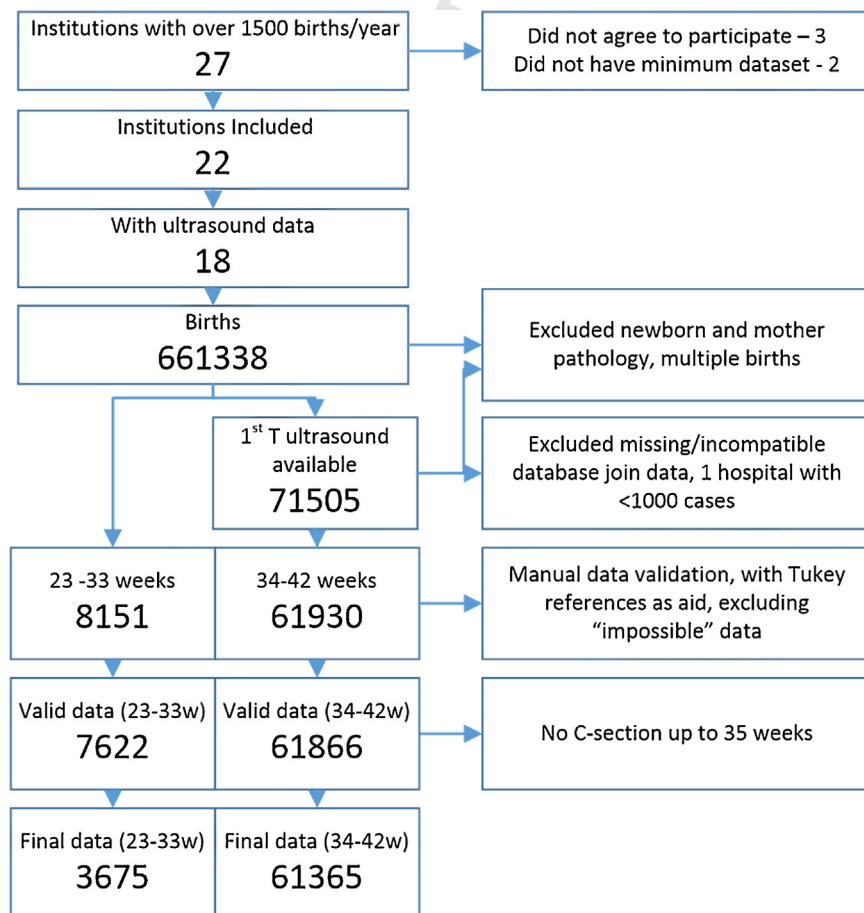


Fig. 1. Flowchart for data collection/validation.

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