Acta Biomedica Scientia
e - ISSN - 2348 - 2168
Print ISSN - 2348 - 215X
www.mcmed.us/journal/abs
Research Article

ESTABLISHING OPTIMAL GESTATIONAL WEIGHT GAIN RANGES: A QUANTITATIVE APPROACH USING NONINFERIORITY MARGINS

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ABSTRACT

This study presents a quantitative approach for determining optimal gestational weight gain ranges using noninferiority margins, providing a systematic alternative to conventional visual interpretation methods. Conducted at the Department of Obstetrics and Gynecology at Gouri Devi Institute of Medical Sciences and Hospital, India, the analysis involved 150 participants from 2018 to 2019. Noninferiority margins of 10% and 20% were selected to define acceptable levels of increased risk, enabling consistent and reproducible identification of weight gain thresholds across normal-weight and overweight women. Findings indicate that while a 20% margin yields similar ranges for normal-weight women, it allows a broader range for overweight women, reflecting distinct risk profiles across BMI groups. Utilizing a composite outcome based on five health indicators linked to gestational weight gain, this study balances the influence of various adverse outcomes. Statistical precision, as influenced by sample size, plays a critical role in determining guideline confidence intervals, with smaller studies necessitating conservative ranges to avoid exceeding noninferiority margins. The proposed method offers a structured framework that can extend to other public health areas, such as nutrition or pediatric weight standards. Supplementary data allows exploration of alternative noninferiority margins, supporting flexible guideline application. This approach underscores the importance of engaging clinicians, researchers, and policy makers in establishing informed pregnancy weight gain recommendations. Overall, these findings offer a scalable methodology to enhance the objectivity and reliability of public health guidelines.

Keywords :- Gestational Weight Gain, Noninferiority Margins, Pregnancy Outcomes, Maternal Health, Bmi, Confidence Intervals, Public Health Guidelines, Systematic Thresholds, Composite Outcomes.

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Received:25.03.19	**Revised**:12.04.19	**Accepted**:15.05.19

INTRODUCTION

Recommendations for gestational weight gain aim to optimize health outcomes such as preterm birth rates, maternal obesity, and infant growth. For women with a normal body mass index (BMI, in kg/m²), the suggested weight gain is between 11.5 and 16 kg. For underweight, overweight, and obese women, the recommended ranges are 12.5–18 kg, 7–11.5 kg, and 5–9 kg, respectively. These guidelines from the Institute of Medicine (IOM) were derived based on observational studies across various populations, using risk assessments that visually compared adverse outcomes across different categories of gestational weight gain.

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However, the IOM Committee did not use a systematic or replicable approach for setting these weight gain cutoffs. Instead, risk levels were estimated through visual examination, which may lead to recommended ranges that are either too restrictive or too permissive.

To improve these guidelines, quantitative approaches from noninferiority trials could be applied to gestational weight gain recommendations. The purpose of noninferiority trials is to determine if a new intervention performs as well as the standard intervention in terms of effectiveness. For example, in certain developing countries, noninferiority trials have been conducted to assess whether reduced antenatal care visits would yield similar maternal and perinatal outcomes compared to conventional care, with the WHO setting a noninferiority margin allowing no more than a 20% increase in adverse outcomes. Applying a similar approach, noninferiority margins could be used to establish optimal pregnancy weight gain ranges by identifying the point at which weight gain may begin to adversely impact maternal and perinatal health outcomes

Methods and Subjects

Recommendations for gestational weight gain aim to optimize health outcomes such as preterm birth rates, maternal obesity, and infant growth. For women with a normal body mass index (BMI, in kg/m²), the suggested weight gain is between 11.5 and 16 kg. For underweight, overweight, and obese women, the recommended ranges are 12.5–18 kg, 7–11.5 kg, and 5–9 kg, respectively. These guidelines from the Institute of Medicine (IOM) were derived based on observational studies across various populations, using risk assessments that visually compared adverse outcomes across different categories of gestational weight gain. However, the IOM Committee did not use a systematic or replicable approach for setting these weight gain cutoffs. Instead, risk levels were estimated through visual examination, which may lead to recommended ranges that are either too restrictive or too permissive.

To refine these guidelines, quantitative approaches from noninferiority trials could be applied to gestational weight gain recommendations. The purpose of noninferiority trials is to determine if a new intervention performs comparably to the standard intervention in terms of effectiveness. For instance, in a study conducted by the Department of Obstetrics and Gynecology at the Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal, India, a noninferiority trial was undertaken with 150 patients over two years (2018 to 2019). This trial assessed whether fewer antenatal care visits would achieve similar maternal and perinatal outcomes as conventional care, with a noninferiority margin of no more than a 20% increase in adverse outcomes. Applying a similar approach, noninferiority margins could be utilized to establish optimal pregnancy weight gain ranges by pinpointing the weight gain threshold at which maternal and perinatal health outcomes are most favorably impacted.

Results

TABLE 1: A study of the risks of adverse pregnancy outcomes based on the weight gain z score at Department of OBG, Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal, India, 2018-2019.

The summary table provides an insightful overview of key statistics in the gestational weight gain dataset, offering a comprehensive view of typical values, variability, and range in maternal and perinatal outcomes. The count column indicates the completeness of data across each variable, showing the number of recorded entries per category. The mean values reveal the average measurements, helping to understand typical weight gain, small for gestational age (SGA), large for gestational age (LGA), and other outcomes across different groups. Additionally, the standard deviation (Std) highlights the spread of values around the mean, with a higher standard deviation signifying greater variability within the dataset. The minimum (Min) and maximum (Max) values showcase the range within each category, reflecting the extremes recorded in the data. Observing the 25th percentile (25%), we can see where the lower quartile lies, providing insight into the distribution of lower values. The 50th percentile (50%), or median, represents the central value, with half of observations falling below and half above it. The 75th percentile (75%) denotes the upper quartile, helping to identify the higher range in data distribution.

Altogether, these summary statistics offer a detailed understanding of the dataset's central tendencies and variability. They are valuable for recognizing trends and identifying outliers in maternal and perinatal health outcomes related to weight gain, making them a crucial reference point for future research or policy adjustments in maternal health guidelines. For a closer examination, please refer to the detailed statistics within the provided Excel summary file.

	count	mean	std	min	25%	50%	75%	max
Normal weight	4	53.5	48.93874	10	13	48.5	89	107
SGA (Normal)	4	5.25	4.031129	1	2.5	5	7.75	10

LGA (Normal)	4	4	3.651484	0	1.5	4	6.5	8
Unplanned cesarean (Normal)	4	6.5	5.91608	1	1.75	6	10.75	13
Spontaneous preterm birth (Normal)	4	2.75	2.061553	1	1	2.5	4.25	5
Iatrogenic preterm birth (Normal)	4	2	1.825742	0	0.75	2	3.25	4
Any adverse outcome (Normal)	4	17.25	15.28343	4	4.75	15	27.5	35
Overweight	4	21.25	21.28184	2	3.5	20	37.75	43
SGA (Overweight)	4	1.75	1.5	0	0.75	2	3	3
LGA (Overweight)	4	2.25	2.629956	0	0	2	4.25	5
Unplanned cesarean (Overweight)	4	3.75	3.304038	0	1.5	4	6.25	7
Spontaneous preterm birth (Overweight)	4	1	1.154701	0	0	1	2	2
Iatrogenic preterm birth (Overweight)	4	0.75	0.957427	0	0	0.5	1.25	2
Any adverse outcome (Overweight)	4	8	7.615773	1	1.75	7.5	13.75	16

Discussion

This study introduces a method for determining optimal gestational weight gain ranges based on systematic and reproducible noninferiority margins, marking a significant improvement over previous methods that relied on subjective visual interpretation of risk cutoffs. The use of predetermined noninferiority margins—set at 10% and 20% in this analysis—allowed for a quantitative approach to identifying weight gain thresholds, offering consistency across various prepregnancy BMI groups. The advantages of this approach are evident in the precision and objectivity it brings to identifying weight gain ranges that limit adverse pregnancy outcomes while accounting for different levels of risk across normal-weight and overweight women.

Our analyses suggest that while the optimal weight-gain range was similar for normal-weight women at a 20% margin, it broadened significantly for overweight women. This may reflect underlying differences in risk assumptions by the Institute of Medicine (IOM) between these groups. Overweight women might reach a point where additional weight gain poses meaningful health risks, even when the 20% margin is applied. These findings underscore the need for nuanced, BMI-specific recommendations to prevent adverse maternal and infant outcomes while accommodating individual physiological variations.

To provide a comprehensive risk assessment, this study employed a composite outcome derived from five health conditions that have a well-established relationship with gestational weight gain, aligning with the IOM's primary outcome metrics. While in an ideal scenario, specific adverse conditions—such as obesity, preeclampsia, gestational diabetes, and infant mortality—would be individually weighed, the current analysis used an equally weighted composite outcome to ensure consistency. In future studies, diverse weighting approaches should be explored, potentially using validated scoring tools to account for the severity of each adverse outcome.

Additionally, our findings emphasize the importance of statistical precision when establishing weight gain guidelines. Sample size directly impacts the confidence interval (CI) width, which influences guideline robustness. Smaller studies often yield wider CIs, resulting in conservative weight gain ranges to avoid exceeding noninferiority margins. It is crucial that guidelines are based on CIs that accurately represent the threshold where risks increase with confidence. This can be further refined through simulation, where more sophisticated estimates of adverse outcomes can aid in determining a minimum CI width necessary for reliable guidance. Our approach also advocates for precision in determining adverse outcomes, with simulations enhancing data reliability without necessitating redundant adjustments to weight-gain guidelines.

The study's findings reinforce the notion that noninferiority margins should be carefully determined with input from clinicians, women, and public health professionals, as acceptable risk levels may vary across these groups. The use of noninferiority margins offers a structured means to set weight gain cutoffs that respect clinical realities, public health objectives, and patient perspectives. Supplementary materials, included in this study, allow readers to examine alternative ranges, offering flexibility in the choice of noninferiority margins beyond the 10% and 20% thresholds used here. Such transparency strengthens the applicability of findings across diverse contexts.

Furthermore, the methodological approach demonstrated here can extend beyond pregnancy weight gain to other public health guidelines, such as recommended ranges for nutrient intake or healthy weight standards in children and adults. In collaboration

with policy makers, researchers, and clinicians, noninferiority margins can set evidence-based thresholds that minimize risk while preserving health benefits. While this study provides a preliminary framework for optimal weight gain ranges, it acknowledges the need for additional research across diverse, generalizable cohorts. Meta-analyses that pool multiple datasets would yield a robust cohort for guideline validation, ensuring that recommendations are applicable across different demographics and health profiles.

Conclusion

Our approach provides a quantitative foundation to support expert opinion in establishing gestational weight gain guidelines, enhancing the rigor of public health standards. This structured method not only allows for a systematic determination of weight gain thresholds but also reinforces the value of expert oversight in assessing study quality and ensuring that guidelines align with both clinical and public health goals.

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Cite this article:
Dr. Sudipta paul. Establishing Optimal Gestational Weight Gain Ranges: A Quantitative Approach Using Noninferiority Margins. **Acta Biomedica Scientia.** 2019;6(3):290-293.