Prenatal testing

Success of NIPT based on Maternal Weight and Gestational Age

Jenna Wardrop, Theresa Boomer, Eyad Almasri, Samantha Caldwell, Sidra Boshes, Ron McCullough

Sequenom Laboratories® San Diego, CA, Laboratory Corporation of America® Holdings

Poster presented at the *NSGC Annual Conference*, 2016 September 28-October 1; Seattle, WA.

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I. INTRODUCTION

The use of cell-free DNA (cfDNA) has increasingly become the standard of care for prenatal screening of fetal aneuploidy. Unfortunately, NIPT has the potential to yield a non-reportable result, as such, it is important to understand the factors impacting the ability to obtain a clinical result. Maternal weight has an inverse relationship to fetal fraction, while fetal fraction has a direct relationship with gestational age. This study reviews the success rate of obtaining an NIPT result as a function of maternal weight and gestational age (GA).

II. METHODS

A retrospective analysis of 244,310 maternal blood samples that were submitted to Sequenom Laboratories for MaterniT® 21 Plus laboratory developed testing were stratified by maternal weight and gestational age. The percent of NIPT samples that yielded a non-reportable test result was evaluated assuming both factors are independent. Samples were subjected to DNA extraction, library preparation, and whole genome massively parallel sequencing as described by Jensen et al.[1]

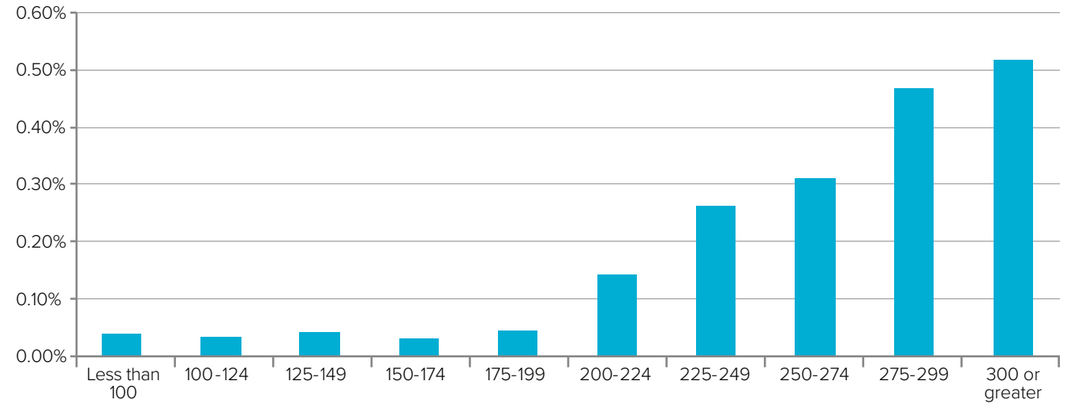
III. RESULTS

The average GA and maternal weight is 14.4 weeks at 161 lbs and a success rate of 98.5%. Patients <125 lbs have 100% success rate at GA >27 weeks, the lowest success rate is in the highest weight population >300 lbs at 91.6% (ranging from 89.5-100% depending on GA). Stratifying these populations by GA shows only a minor impact in success rate across GA in the <200 lbs population, but a marked improvement as GA increases, matching the average population success rate in the heaviest population at 25 weeks GA.

Table 1. Success rate by gestational age and maternal weight

Gestational Age (weeks) \ Maternal Weight (lbs)	Less than 100	100 - 124	125 - 149	150 - 174	175 - 199	200 - 224	225 - 249	250 - 274	275 - 299	300 or greater	Average
10-12	99.6%	99.4%	99.1%	98.7%	97.8%	96.6%	94.7%	92.6%	91.0%	89.5%	98.3%
13-15	99.6%	99.3%	99.3%	98.8%	98.0%	96.4%	94.9%	92.0%	90.7%	88.8%	98.2%
16-18	98.5%	99.3%	99.5%	98.9%	98.3%	97.8%	97.1%	94.9%	93.1%	94.2%	98.5%
19-21	100.0%	99.5%	99.5%	99.1%	98.9%	98.9%	98.2%	96.6%	96.9%	97.1%	99.1%
22-24	100.0%	99.5%	99.2%	99.3%	99.3%	99.1%	98.5%	99.7%	98.8%	96.6%	99.2%
25-27	100.0%	99.3%	98.8%	99.2%	98.6%	98.9%	99.3%	98.6%	98.4%	98.6%	98.9%
28-30	100.0%	100.0%	98.8%	99.7%	98.9%	98.8%	99.4%	98.7%	98.2%	97.6%	99.1%
>30	100.0%	100.0%	98.3%	99.0%	98.6%	99.6%	100.0%	96.9%	100.0%	100.0%	98.7%
Average	**99.5%**	**99.3%**	**99.2%**	**98.8%**	**98.1%**	**97.1%**	**95.8%**	**93.5%**	**92.3%**	**91.6%**	**98.5%**

Graph 1. Weekly increase in success rate by maternal weight



IV. CONCLUSIONS

Of the two factors studied, GA and maternal weight, the later has a larger impact on NIPT success rate but it can be improved with an increase in GA. Despite a reduced success rate at extreme maternal weights, especially at early gestational age, cfDNA testing delivers results for more than 91.6% of patients in the >300 lbs population. In this study we show that the not reportable rate of maternal weight on NIPT results can be improved by waiting to test at a later GA for patients >200 lbs. NIPT can be considered a viable option for aneuploidy screening in obese patients.

V. REFERENCES

1. Jensen TJ1, Zwiefelhofer T, Tim RC, et al. High-throughput massively parallel sequencing for fetal aneuploidy detection from maternal plasma. *PLoS One*. 2013; 8(3):e57381. doi:10.1371/journal.pone.0057381. Epub 2013 Mar 6.

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