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ORIGINAL RESEARCH

Effectiveness of Fetal Medicine Foundation's Non-Biochemical Risk Calculation Algorithm in Detection of Common Trisomies Screening at 11–13 weeks of Gestation: 12 Years' Experience in Northern Thailand

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Purpose: To evaluate the efficacy of first-trimester non-biochemical screening using the Fetal Medicine Foundation (FMF) algorithm in predicting fetal common trisomies (trisomy 21, 18, and 13) in clinical practice.

Patients and Methods: Between 2011 and 2023, the non-biochemical screening was routinely performed at 11+0-13+6 weeks' gestation in 9591 singleton pregnancies at Maharaj Nakorn Chiang Mai Hospital, Thailand. The individual risks for common fetal trisomies were calculated by combining maternal age, history of common trisomies in a previous pregnancy, nuchal translucency thickness, and fetal heart rate using the official FMF algorithm. Women with risk of ≥1:250 were classified as high risk. The fetal karyotyping results and pregnancy outcomes were reviewed and analyzed.

Results: A total of 8491 complete data sets of singleton pregnancies were analyzed. The incidence of common trisomies was 0.5% (46 cases), including 0.3% (28 cases) of trisomy 21, 0.1% (9 cases) of trisomy 18 and 0.1% (9 cases) of trisomy 13. With a cut-off risk of 1:250, FMF algorithm performance for trisomy 21 screening had a sensitivity of 60.7%, specificity of 97.6%, PPV of 7.7%, NPV of 99.9%, and a false positive rate of 2.4%. The performance for detecting all common trisomies demonstrated a sensitivity of 52.2%, specificity of 97.2%, PPV of 9.2%, NPV of 99.7%, and a false positive rate 2.8%.

Conclusion: The first trimester non-biochemical FMF algorithm is sufficiently effective in predicting common trisomies, particularly trisomy 21. This simple approach can be easily implemented in clinical practice, including healthcare facilities that lack access to maternal blood testing services.

Keywords: trisomy, down syndrome, prenatal screening, first trimester screening, nuchal translucency

Introduction

Common trisomies, such as trisomy 21, 18, and 13, are chromosomal abnormalities characterized by an extra chromosome, which poses a risk to all pregnancies, with a higher incidence in women aged 35 and older. Universal screening is recommended for early identification, offering pregnant women options for termination or counseling to prepare for neonatal management. Standard screening methods include maternal serum biochemical analytes in the first and early second trimesters, as well as cell-free DNA testing, which is the most accurate method.[1] However, these methods face challenges in some countries, such as limited availability, high costs, and logistical delays in receiving test results.

Screening methods that do not rely on maternal blood tests, such as ultrasound markers, may also be utilized, although they have lower detection rates. The most common ultrasound marker is fetal nuchal translucency (NT) evaluation in the first trimester, which is recommended for every pregnancy.[2,3] NT measurement can be combined with maternal history and other non-biochemical markers, such as fetal heart rate (FHR), to improve screening

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performance.[4] This data can be processed using the Fetal Medicine Foundation (FMF) algorithm, accessible via its website (fetalmedicine.org).[5] Research-based studies in Western populations suggest that this method can achieve a screening efficiency of up to 80%.[6]

This clinical practice-based study aims to evaluate the efficacy of screening for trisomy 21, 18, and 13 in Asian pregnant women at 11–13 weeks of gestation by using maternal characteristics, fetal NT measurements, and FHR to calculate individual risk via the FMF algorithm, without the inclusion of maternal biochemical markers. This approach provides same-day results, enabling timely risk assessment and facilitating shared decision-making between healthcare providers and pregnant women for further prenatal diagnosis and management.

Material and Methods

This diagnostic study, as a secondary analysis on the database, was conducted on pregnant women at 11+0–13+6 weeks of gestation who underwent screening for common trisomies at Maharaj Nakorn Chiang Mai Hospital, Thailand, between January 2011 and December 2023. This study was conducted in accordance with the guidelines of the Declaration of Helsinki and was ethically approved by the Institutional Review Board, Faculty of Medicine, Chiang Mai University (Research ID: OBG-2566-0133, approval date 12 May 2023). Due to its retrospective design, the requirement for informed consent was waived. All data were fully anonymized before analysis to ensure the confidentiality and privacy of participants.

Inclusion criteria were singleton pregnancies within the specified gestational age range, with confirmed gestational age and complete ultrasound measurements of crown-rump length (CRL), nuchal translucency (NT), and fetal heart rate (FHR) obtained during the same visit. All sonographers who performed the first-trimester ultrasound examinations were either certified by the FMF or had completed equivalent local training aligned with FMF standards. Although FMF certification was not mandatory, standardized protocols for measuring NT and FHR were consistently followed, with regular internal quality assurance procedures implemented throughout the study period. Exclusion criteria included pregnancies with non-chromosomal congenital anomalies, medically indicated terminations before 24 weeks of gestation, unmeasurable NT, or missing essential data required for risk calculation. Cases with incomplete data were excluded prior to enrollment, and no imputation was performed.

Maternal characteristics (eg, date of birth, history of trisomy) and ultrasound findings were used to calculate individual risks for trisomy 21, 18, and 13 using the Fetal Medicine Foundation (FMF) algorithm via its online platform (https://fetalmedicine.org/research/assess/trisomies). For instance, in a 35-year-old woman with a fetal CRL of 65 mm, an NT of 2.5 mm, an FHR of 165 bpm, and no prior history of trisomies, the algorithm may generate an estimated risk of 1:220 for trisomy 21, classifying the pregnancy as high risk based on the predefined cut-off of ≥1:250.

Risk for each trisomy was categorized into two groups: low risk (<1:250) and high risk (>1:250). Pregnancy outcomes, including fetal or neonatal karyotyping results, gestational age at delivery, birth weight, and any complications, were recorded. Neonatal outcomes were classified as either normal or affected by common trisomies. Pregnancy outcomes were confirmed by neonatal physical examination in all participants. Fetal karyotyping was performed in cases undergoing invasive prenatal diagnostic procedures. In the absence of clinical abnormalities, neonates were presumed to be chromosomally normal.

Data were analyzed using IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp). The study aimed to evaluate the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), false positive rate (FPR), and false negative rate (FNR) of the FMF's non-biochemical risk calculation in predicting common trisomies. A p-value of <0.05 was considered statistically significant.

Results

A total of 9591 participants were enrolled in the study. Of these, 1100 participants were excluded due to incomplete data (73.4%), unmeasurable NT (14.6%), medically indicated abortion (9.4%), and other chromosomal abnormalities (2.6%), which included monosomy X, chromosomal deletions, mosaicism, and inversion. The remaining 8491 participants were analyzed and classified as either normal or affected by common trisomies, as illustrated in Figure 1. The incidence of all common trisomies, trisomy 21, trisomy 18, and trisomy 13 in our study was 1:200, 1:333, 1:1000, and 1:1000, respectively.

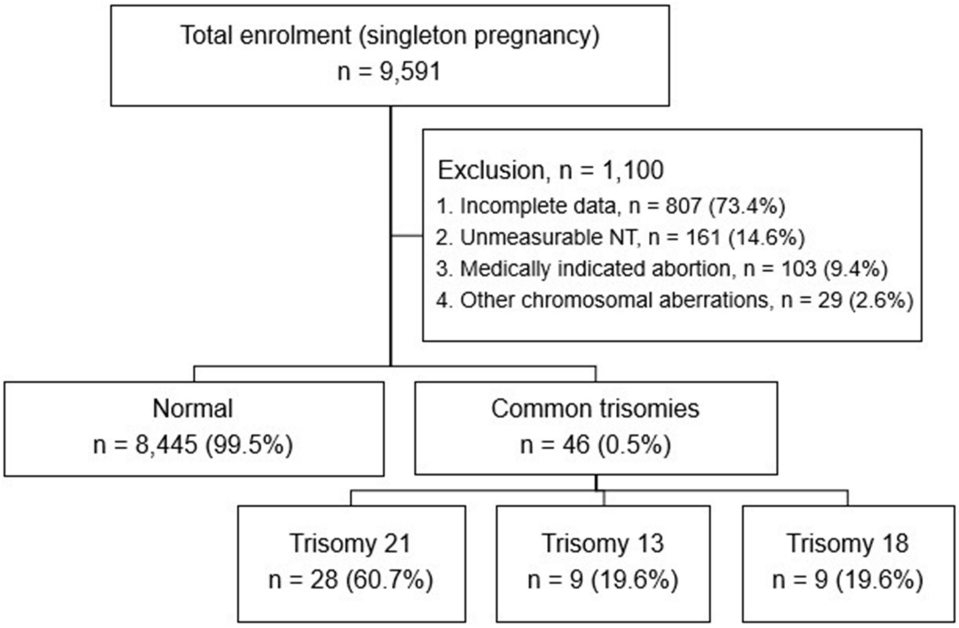

Figure 1 A Flow Diagram of the Study Participants.

A total of 1684 women (19.8% of the population) were aged of 35 years or greater. Maternal age ranged from 13 to 45 years, with the average age in the affected group being significantly higher at 33 years compared to 30 years in the normal group (p = 0.001). Additional baseline characteristics of the study population are presented in Table 1.

Table 1 Baseline Characteristics of Participants in the Study Cohort

Variable	Normal (n = 8445)	Common Trisomies (n = 46)	*P*-value
Maternal age, year	30 (7)	33 (10)	0.001[a]
Maternal age ≥35-year, n (%)	1665 (19.7%)	19 (41.3%)	0.001[b]
Maternal body weight, kg	54.2 (12.8)	54.6 (11.8)	0.981[a]
GA at screening, week	12 (1)	12 (1)	0.434[a]
CRL, mm	61.9 (14.5)	62.0 (22.3)	0.531[a]
NT, mm	1.2 (0.5)	1.9 (2.1)	<0.001[a]
FHR, bpm	162 (8)	163 (9)	0.349[a]
NT ≥3 mm, n (%)	51 (0.6%)	15 (32.6%)	<0.001[b]
FMF risk for T21 ≥1:250, n (%)	199 (2.4%)	23 (50.0%)	<0.001[b]
FMF risk for T18 ≥1:250, n (%)	65 (0.8%)	16 (34.8%)	<0.001[b]
FMF risk for T13 ≥1:250, n (%)	41 (0.5%)	9 (19.6%)	<0.001[b]
FMF risk for T21, T18, or T13 ≥1:250, n (%)	236 (2.8%)	24 (52.2%)	<0.001[b]
GA at delivery, week	38 (1)	21 (6)	<0.001[a]
Neonatal birth weight, gm	3030 (565)	320 (400)	<0.001[a]

Notes: Data are presented as median (interquartile range) or as number (percentage). a Chi-square, b Mann–Whitney-*U* test.
Abbreviations: CRL, crown rump length; FHR, fetal heart rate; GA, gestational age; NT, nuchal translucency.

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Table 2 Performance of the Fetal Medicine Foundation (FMF) Non-Biochemical Algorithm in Predicting Common Trisomies

Diagnostic Statistics	T21	T21, T18, or T13
Sensitivity, % (95% CI)	60.7 (42.6–78.8)	52.2 (37.7–66.6)
Specificity, % (95% CI)	97.6 (97.3–98.0)	97.2 (96.9–97.6)
Likelihood ratio (95% CI)	25.0 (18.1–34.8)	19.6 (14.9–25.9)
Positive predictive value, % (95% CI)	7.7 (4.2–11.1)	9.2 (5.7–12.7)
Negative predictive value, % (95% CI)	99.9 (99.8–99.9)	99.7 (99.6–99.8)
False positive rate, %	2.4	2.8

Table 3 Performance of the Fetal Medicine Foundation (FMF) Non-Biochemical Algorithm in Predicting Common Trisomies in a Subgroup of Pregnant Women Aged Younger Than 35 years

Diagnostic Statistics	T21	T21, T18, or T13
Sensitivity, % (95% CI)	50.0 (23.8–76.2)	37.0 (18.8–55.3)
Specificity, % (95% CI)	98.6 (98.3–98.9)	98.2 (97.9–98.5)
Likelihood ratio (95% CI)	35.0 (20.0–61.3)	20.9 (12.4–35.3)
Positive predictive value, % (95% CI)	6.7 (1.9–11.5)	7.7 (3.1–12.3)
Negative predictive value, % (95% CI)	99.9 (99.8–100.0)	99.7 (99.6–99.8)
False positive rate, %	1.4	1.8

As shown in Table 2, the FMF algorithm with a cut-off value of 1:250 demonstrated a sensitivity of 52.2% for detecting all common trisomies, including 60.7% specifically for trisomy 21. The overall specificity for common trisomies was 97.2%, and a specificity of 97.6% for trisomy 21. Performance for trisomies 18 and 13 was not reported due to inadequate sample size. The false positive rate (FPR) for common trisomies was 2.8%, and 2.4% for trisomy 21. A subgroup analysis of women younger than 35 revealed a sensitivity of 37.0% for common trisomies and 50.0% for trisomy 21. The specificity in this subgroup was 98.2% for common trisomies and 98.6% for trisomy 21, as shown in Table 3.

Discussion

Global and ethnic disparities in access to and adherence with first-trimester screening and non-invasive prenatal testing (NIPT) have been increasingly recognized, particularly in minority populations and resource-limited settings.[7] These disparities highlight the importance of accessible alternatives such as non-biochemical screening strategies, which can help bridge the gap in prenatal care. The FMF's common trisomies risk assessment is a free online tool that calculates risk based on a combination of maternal characteristics, fetal nuchal translucency (NT), and fetal heart rate (FHR), with or without maternal serum biochemistry values, such as PAPP-A and free beta-hCG.[5] This study evaluates the performance of FMF's risk calculation in predicting trisomy 21, trisomy 18, and trisomy 13 without maternal serum biochemistry between 11+0 and 13+6 weeks of gestation. The results show that the sensitivity, specificity, and false-positive rate for all common trisomies using a cut-off value of 1:250 were 52.2%, 97.2%, and 2.8%, respectively. For trisomy 21, the sensitivity, specificity, and false positive rate were 60.7%, 97.6%, and 2.4%, respectively.

There are limited studies on first trimester screening for common trisomies or trisomy 21 without using maternal serum biochemistry. Our study is the first to investigate the accuracy of FMF's first-trimester screening using only ultrasound markers (NT and FHR) and maternal characteristics for detecting common trisomies, specifically trisomy 21,

without maternal serum testing. In comparison, a Cochrane review estimated that the sensitivity of NT combined with maternal age for trisomy 21 screening, using a 1:250 cut-off, was 72% with a specificity of 94%.[4] For trisomy 21 screening in our study, using the same cut-off, we observed slightly lower sensitivity but higher specificity, with a low false positive rate. Furthermore, our findings show a higher detection rate for trisomy 21 compared to using NT measurement alone in the same population, as observed in a previous study, where NT alone achieved a detection rate of 55% with a 5% false positive rate.[8] A major advantage of FMF's algorithm compared to using NT alone with a 3 mm cut-off is its ability to provide an individualized risk estimate for each pregnancy. This personalized assessment supports healthcare providers and couples in making informed decisions about further testing or prenatal diagnosis. In comparison with other studies using the FMF algorithm, the detection rate for trisomy 21 in our study is lower than that reported in a multicenter study from the UK, which assessed risk based on maternal age and NT measurements at 10–14 weeks of gestation. That study applied a lower risk cut-off of 1 in 300, resulting in a higher sensitivity of 82.2% but also a higher false positive rate of 8.3%.[6] Similarly, a study from the United States evaluated trisomy 21 risk between 11 and 14 weeks of gestation using FMF software based on maternal age and NT, and reported a sensitivity of 81.3% with a false positive rate of 7.2% using the same 1 in 300 cut-off.[9]

Compared to second trimester serum screening, a prospective study of the quadruple test based on our local (Thai) reference ranges reported a sensitivity of 76.2% and a false-positive rate of 9.2% for trisomy 21 screening.[10] Although the detection rate of the quadruple test is higher than our findings, the high rate of invasive prenatal diagnostic procedures due to false positives is a concern, partly attributed to logistical and temperature control issues during blood sample collection and transportation from various hospitals to a central lab.[11] FMF's algorithm, which relies on ultrasound markers and maternal characteristics without the need for biochemistry, could help address this issue, particularly for small or remote hospitals with limited facilities.

In our study, the screen-positive rate for FMF's non-biochemical risk calculation was 3.1% for common trisomies and 2.6% for trisomy 21, aligning with the 3.7% screen positive rate reported in a previous study using FMF software for combined first-trimester screening in private antenatal care.[12] The screen positive rate in prenatal screening is crucial, as it indicates how many pregnant women are identified as high risk. A higher screen positive rate results in more women undergoing invasive prenatal diagnostic procedures, which carry an increased risk of fetal loss. The lower screen positive rate observed in our study may help reduce unnecessary interventions and patient anxiety, while still allowing for early detection of common trisomies.

According to the American College of Obstetricians and Gynecologists (ACOG), NIPT using cell-free DNA (cfDNA) in maternal circulation is the most sensitive screening test for common fetal aneuploidies, with a detection rate of 99%, a false positive rate of less than 1%, and a screen positive rate of 2–4% for trisomy 21.[1] Due to its exceptional performance, the use of NT measurement and first- and second-trimester serum biochemistry screening has declined since the introduction of cfDNA into clinical practice.[13,14] However, NIPT is costly, making it less cost-effective as a first-line screening tool, especially in developing countries, where it is better suited as a second-line test if the initial screening results are equivocal or indicate moderate risk.[15] In Thailand, a cost-benefit analysis of prenatal screening methods—including first-trimester screening, NIPT, and invasive prenatal diagnosis—identified first-trimester screening as the most cost-beneficial. Reducing the cost of NIPT by 80%, from 237 USD to 47 USD, would make it cost-effective compared to first-trimester screening.[16] Moreover, high-resolution ultrasound in the first trimester has the potential to detect certain fetal anomalies before 14 weeks,[17] reinforcing the importance of NT measurement during ultrasound exams at 11–13+6 weeks as recommended by several major organizations.[1–3,18]

In this study, the prevalence of all common trisomies, trisomy 21, trisomy 18, and trisomy 13 per 1000 births was 5.42, 3.30, 1.06 and 1.06, respectively. These rates are comparable to findings from other regions in our country.[19,20] In the subgroup analysis of women under 35, FMF's non-biochemical risk estimation for trisomy 21 showed a sensitivity of 50.0%, a specificity of 98.6%, and a false positive rate of 1.4%. Due to its high specificity, the FMF algorithm could be used for general population screening as a triage test. For instance, women with low FMF risk can defer NIPT or first-trimester maternal serum marker tests and opt for the quadruple test in the second trimester, which is covered by Thailand's Universal Health Coverage. In cases of high FMF risk, more accurate screening tests can be offered promptly without delaying diagnosis. The FMF non-biochemical algorithm can serve as a one-stop service during the first-trimester ultrasound, providing

essential information for genetic counseling and decision-making. Its simplicity and ease of use make it applicable in various healthcare settings, including private clinics or hospitals, particularly in low- and middle-income countries where access to maternal blood testing or NIPT may be limited. However, this method cannot be used in facilities without ultrasound capabilities for NT measurement or for women presenting for antenatal care after 14 weeks of gestation.

This study has several limitations. First, its retrospective design led to some data loss, including the exclusion of cases with missing or unmeasurable NT measurements. These excluded cases may have introduced selection bias, as they could represent higher-risk pregnancies—such as those with fetal anomalies, maternal obesity, or suboptimal fetal position—that made NT measurement technically difficult. As a result, the exclusion of these cases may have slightly underestimated the sensitivity of the screening algorithm. Second, verification bias may exist, as not all fetuses underwent karyotyping, and normal outcomes were assumed based on neonatal physical examination in the absence of clinical abnormalities. Finally, the relatively small number of cases with trisomy 13 and trisomy 18 limits the interpretability and precision of the sensitivity estimates for these conditions, despite sufficient statistical power (90%) for trisomy 21 detection.

A key strength of this study is its large sample size and long-term data collection over a 12-year period, which enhances the reliability of the findings. Moreover, the first-trimester ultrasound examinations were conducted as part of routine clinical practice rather than a research setting, making the results more applicable to real-world scenarios and generalizable to similar healthcare environments. The use of standardized protocols and certified sonographers further supports the consistency and quality of the data.

Future studies should include prospective validation of the non-biochemical FMF algorithm to confirm its performance across diverse populations. Cost-effectiveness analyses comparing this approach to NIPT and conventional combined screening are warranted, especially in resource-limited settings. Additionally, incorporating the algorithm into hybrid screening models—such as contingent or sequential testing strategies—may help optimize detection rates while minimizing costs and unnecessary invasive procedures.

Finally, our study findings have important public health implications. The use of a non-biochemical FMF algorithm for first-trimester screening offers a practical and cost-effective option for early detection of common trisomies, particularly in settings with limited access to maternal serum biochemistry or NIPT. By enabling wider implementation of prenatal screening in low- and middle-income countries like Thailand, this approach could help reduce disparities in access to care and support the development of national screening recommendations that are both effective and feasible within existing healthcare infrastructures.

Conclusion

In conclusion, the first-trimester non-biochemical FMF algorithm is sufficiently effective in predicting common trisomies, particularly trisomy 21. This straightforward approach can be easily integrated into clinical practice, making it particularly valuable in healthcare settings without access to maternal blood testing services, especially in low- and middle-income countries.

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Disclosure

The authors report no conflicts of interest in this work.

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