Fetal Nuchal Translucency Measurements: Performance of Midwives and Doctors Compared

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Objective: To compare (a) the performances in fetal nuchal translucency for multiple of median, and false-positive Down syndrome detection rates in doctors and midwives, and (b) the same parameters as obtained using the two models of ultrasound machines.
Methods: We conducted a retrospective review of all pregnancies with fetal nuchal translucency measurements in a public hospital in Hong Kong from July 2010 to December 2011. We compared demographic factors, fetal nuchal translucency multiple of median values, and false-positive Down syndrome detection rates by doctors and midwives. We also compared the same parameters obtained by the two models of ultrasound machines (Philips IU22 [US] and Medison V20 [Korea]) that were used. Both the doctors and midwives responsible for fetal nuchal translucency measurements were certified Hospital Authority sonographers who had completed the Fetal Medicine Foundation training, and were supervised until deemed fit for independent scanning, and their performance was monitored. A standardised protocol for fetal nuchal translucency measurements was adopted from Fetal Medicine Foundation. Both models of the ultrasound machines were equipped with high-resolution ultrasound probes. A pre-set protocol for measuring nuchal translucency was available in both machines. Independent paired *t* tests and Chi-square tests were used to analyse the parametric and non-parametric data, respectively.
Results: A total of 5983 first-trimester screens for Down syndrome were performed from July 2010 to December 2011. Among these, 1262 (21.1%) and 4721 (78.9%) screenings were performed by doctors and midwives, respectively. In all, 5746 (96.0%), 217 (3.6%), and 9 (0.2%) of the fetal nuchal translucency measurements were performed using the Philips IU22, Medison V20, and another ultrasound machine, respectively. Between doctors and midwives, there were no differences in the mean fetal nuchal translucency multiple of median values (0.97 vs. 0.98; p=0.081), the false-positive rates (7.1% vs. 5.8%; p=0.15), and the Down syndrome detection rates (100% vs. 94.1%; p=0.742). There was also no difference in the mean nuchal translucency multiple of median values obtained by the two models of ultrasound machines (Philips IU22 and Medison V20) being compared, respective values being 0.98 vs. 1.01 (p=0.152).
Conclusion: It seems that the performance of trained midwives in measuring fetal nuchal translucency is comparable to that of trained doctors. Our preliminary results did not show a significant difference in fetal nuchal translucency multiple of median values obtained by the two ultrasound machines when using standardised settings.
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Introduction

First-trimester combined screening is recognised as an effective method for assessing the risk of Down syndrome[1,2]. However, effective screening utilising fetal nuchal translucency (NT) measurements is dependent on appropriate training of sonographers, adherence to a standard ultrasound technique, and regular audit of the results[3-6]. Universal prenatal Down syndrome screening has been offered as a free option in all Hong Kong public hospitals since July 2010. In our obstetrics department, more than 90% of women opted for first-trimester screening, in which fetal NT measurements were a mandatory part of the process.

Because of limited medical manpower, our obstetrics department trained midwives to undertake obstetric ultrasound measurements of NT in low-risk pregnancies. Doctors were responsible for screening high-risk cases (e.g. previous pregnancies with trisomy or chromosomal abnormalities) as well as government servants, Hospital Authority (HA) staff and their dependents. The majority of measurements were performed using a Philips

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IU22 machine (Philips, USA). A small proportion of measurements was performed with a machine equipped with 3D/4D ultrasound (Medison V20; Korea).

Before commencement of the service, both the doctors and midwives responsible for fetal NT measurements were certified as HA sonographers who could offer independent obstetric ultrasonography services in the hospital. In addition, they had completed the theory course organised by the Fetal Medicine Foundation (FMF) and undergone proper training and assessment for fetal NT measurements.

Although performance with respect to NT measurements by doctors or sonographers has been well reported[7], that by midwives has only been reported in a small study[8]. Moreover, the performance obtained using two different machines has not been reported. The objectives of the present study were to compare performance for the measurement of fetal NT in (1) doctors versus midwives, and (2) using two different ultrasound machines. Our hypotheses were that training, staff accreditation, and machine settings were similar, and hence performance in the two groups and with the two ultrasound machines should be comparable.

Methods

Screening for fetal Down syndrome was performed according to the HA Down syndrome screening protocol. In brief, pregnant women booked at our antenatal clinic before 20 weeks of gestation were offered screening for fetal Down syndrome. Either first-trimester combined screening (fetal NT, pregnancy-associated plasma protein A [PAPPA], serum free beta-human chorionic gonadotropin [fBHCG]) or second-trimester biochemical screening (alpha fetoprotein, fBHCG) was offered to women at 11 to 13^{+6} weeks and 16 to 20 weeks of gestation, respectively.

First-trimester screening was performed from 11 weeks to 13^{+6} weeks, with fetal crown-rump length between 42 and 80 mm. Fetal NT was measured according to the FMF protocol 7. If a structural abnormality was detected during fetal NT measurement, direct invasive testing was considered. Such abnormalities included cystic hygroma, megacystis and omphalocele. Other indications for consideration of direct invasive testing included previous pregnancies with trisomy and chromosomal abnormalities, known parental translocation and inversion.

Maternal blood samples, together with fetal NT measurements obtained, were sent to the Prenatal Diagnosis and Counselling (PDC) laboratory of Tsan Yuk Hospital (TYH) for assay of PAPPA and fBHCG, and calculation of the multiple of median (MoM) of different markers and Down syndrome risk. The cutoff risk for first-trimester Down syndrome screening was 1:250 adjusted to give about a 5% risk of false positives.

Operators

Five doctors and five midwives were responsible for the 5983 first-trimester fetal NT measurements in the study period. All five doctors were either maternal-fetal medicine (MFM) specialists or trained/supervised trainees and all five midwives undertook regular obstetrics ultrasound sessions besides fetal NT measurements. The ultrasound experience of the midwives before starting fetal NT measurements ranged from 2 to 12 (mean, 7) years. For doctors, the corresponding period was shortest for the MFM trainee, and amounted to 7 years, whilst the other doctors had ultrasound experience exceeding 10 to 20 years. Both doctors and midwives responsible for fetal NT measurements were HA-certified sonographers, who had completed the FMF training programme, and were supervised until they were deemed fit for independent scanning, and their performance was monitored.

Ultrasound Machine Settings

Two ultrasound machines, Philips IU22 and Medison V20, were used for fetal NT measurements. Both machines were equipped with high-resolution ultrasound probes. 5 MHz or higher frequency probes were used for fetal NT measurements, with a cine loop function available. Cross calipers with horizontal cross bars were used for NT measurements. Measurement accuracy of up to the nearest 0.1 mm was possible and achieved with both machines. A pre-set protocol for measuring NT was available in both machines.

Measurement of Fetal Nuchal Translucency

For each pregnancy, fetal NT was measured 2 to 3 times, with the maximum NT measurement from the best image recorded on the request form[9]. For a good image, it was magnified such that the fetal head and thorax occupied the whole screen. The fetus had to be in a neutral position so that a mid-sagittal view of the face was obtained. Measurements were taken at the widest part of translucency, with the inner border of the horizontal line of the caliper placed on the line that defined the NT thickness. The gain was turned down to avoid the misplacement of the caliper on the fuzzy edge of the line. Figures 1 and 2 illustrate two fetal NT images obtained by a midwife and a doctor sonographer, respectively.

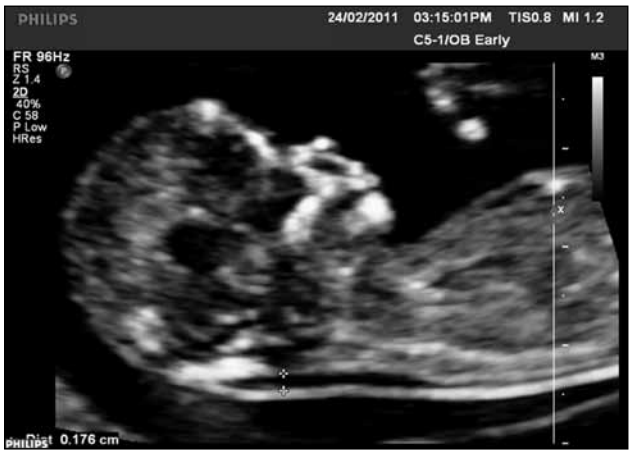

Figure 1. Fetal nuchal translucency measurement by a midwife sonographer

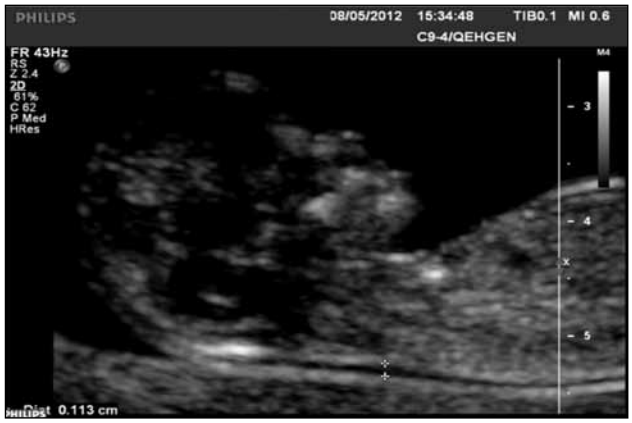

Figure 2. Fetal nuchal translucency measurement by a doctor

Database

A database for Down syndrome screening was set up before commencement of the service in July 2010. We conducted a retrospective review of the database and obtained all fetal NT measurements in our hospital from July 2010 to December 2011. Data on Down syndrome screening, including maternal age at estimated date of confinement (EDC), gestation day at NT measurement, crown rump length, fetal NT, maternal weight, PAPPA and fBHCG MoM, and screening results were also retrieved from PDC laboratory in TYH. Pregnancy outcomes were traced from HA medical record system. For mothers not delivered in HA facilities, the patients were contacted by phone to enquire about pregnancy outcomes.

Monitoring

In each pregnancy, ultrasound images of NT were saved and printed as a hard copy. Abnormal or suspicious cases were referred to an MFM subspecialist for review. The outcomes of all pregnancies were traced by our midwives or supporting staff. Every 3 months, the performance of NT by each operator was externally reviewed by the PDC laboratory in TYH, and individual performance reports were sent to individual operators through the department head.

Outcome Measures

From all the fetal NT measurements, we compared demographic factors, fetal NT MoMs, false-positive rates, Down syndrome detection rates, and fetal abnormality rates as determined by doctors and midwives. The fetal NT MoMs obtained by two ultrasound machines (Philips IU22 and Medison V20) were also compared.

Statistical Analysis

Independent paired *t* tests and Chi-square tests were used to analyse the parametric and non-parametric data, respectively. For statistical analysis, the Statistical Package for the Social Sciences (Windows version 17.0; SPSS Inc, Chicago [IL], US) was used. We addressed mean differences in fetal NT MoM between groups of 0.15 and standard deviation (SD) of 0.1. Assuming α=0.05 (two-sided) and power=0.9, the calculated sample size was 935 per group of operators using sample size tables for clinical studies.

Results

A total of 5983 first-trimester Down syndrome screenings were performed from July 2010 to December 2011. Five doctors and five midwives were responsible for the fetal NT measurements. Nine (90%) of ten sonographers had performed more than 100 scans during the study period (Table 1). The remaining sonographer had resigned during the study period and thus had performed fewer scans. Doctors and midwives performed 1262 (21.1%) and 4721 (78.9%) screenings, respectively. Fetal NT measurements were obtained in 5746 (96.0%), 217 (3.6%), 9 (0.2%) using

Table 1. Nuchal translucency (NT) measurements by doctors and midwives from July 2010 to December 2011

Operator		No. of fetal NT measurements
Doctors (n=1262)	1	327
	2	125
	3	58
	4	241
	5	511
Midwives (n=4721)	1	768
	2	1387
	3	1317
	4	386
	5	863

the Philips IU22, Medison V20, and another ultrasound machine, respectively. The median fetal NT MoM and SD log (10) MoM for our centre was 0.957 and 0.106, respectively. Both were within the reference quality assurance limit of 0.9-1.1 and 0.09-0.13, respectively. Pregnancy outcomes were successfully obtained for 5491 (91.8%) cases. A total of 18 Down syndrome fetuses were detected by first-trimester Down screening, and all except one of the affected mothers opted for termination of pregnancy. During the study period, one Down syndrome baby was detected after birth, after a first-trimester-screen–negative result in the midwife group. Thus, the overall Down syndrome detection rate for our first-trimester Down screening programme was 94.7%.

Doctors Versus Midwives

Differences in the pregnancy characteristics including crown-rump length, gestation day at NT measurement, maternal weight, fBHCG MoM, and maternal age at the EDC in the two groups (doctors and midwives) were significant but small (Table 2).

Between doctors and midwives, there were no differences in the mean fetal NT MoM, false-positive rate, and Down syndrome detection rate (Table 3).

A total of 23 major fetal abnormalities were detected during first-trimester fetal NT measurement (Table 4). The number of fetal abnormalities detected in first-trimester

Table 2. Pregnancy characteristics encountered by midwives and doctors

	Midwives (n=4721)	Doctor (n=1262)	p Value
Mean NT MoM	0.98	0.97	0.081
Crown-rump length	61.2	65.2	<0.001
Gestation day at NT measurement	88.2	90.0	<0.001
Weight (kg)	55.7	54.9	0.006
PAPPA MoM	1.11	1.13	0.269
Free HCG MoM	1.29	1.36	0.016
Age at EDC (years)	31.9	33.1	<0.001

Abbreviations: NT = nuchal translucency; MoM = multiple of median; PAPPA = pregnancy-associated plasma protein A; HCG = human chorionic gonadotropin; EDC = estimated date of confinement

Table 3. Comparison of fetal nuchal translucency performances between the two groups of operators: midwives and doctors

	Midwives (n=4721)	Doctor (n=1262)	p Value
Mean NT MoM	0.98	0.97	0.081
False-positive rate (%)	5.8%	7.1%	0.15
Detection rate (%)	16/17 (94.1%)	2/2 (100%)	0.742

Abbreviations: NT = nuchal translucency; MoM = multiple of median

Table 4. Fetal abnormalities detected during first-trimester fetal nuchal translucency measurements by midwives and doctors

	Midwives* (n=19)	Doctors† (n=4)	Total (n=23)
Anencephaly	5	0	5
Holoprosencephaly	3	1	4
Hydrops	6	2	8
Abdominal wall defects	2	1	3
Cystic hygroma	1	1	2
Megacystis	2	0	2
Major limbs abnormalities	1	1	2
Total No. of fetuses	**19 (0.4%)**	**4 (0.3%)**	**23 (0.4%)**

* One case with co-existing hydrops and abdominal wall defect

† One case with co-existing hydrops and abdominal wall defect, and another case with co-existing hydrops and cystic hygroma

scans were 4 (0.3%) and 19 (0.4%) for doctors and midwives, respectively. This difference was not statistically significant (p=0.610). These fetal abnormalities were all major, suggesting serious structural or chromosomal problems. Further invasive testing, rescanning, and counselling were indicated in all cases.

Two Models of Ultrasound Machines

There was no difference in the mean NT MoM values (0.98 and 1.01) obtained by the two models of ultrasound machines (Philips IU22 and Medison V20) respectively (p=0.152).

Discussion

We showed no difference in the fetal NT MoM values and false-positive Down syndrome detection rates between doctors and midwives. There was also no difference in the detection rates for major fetal abnormalities. During the study period, one Down syndrome baby was detected after birth, after a first-trimester-screen–negative result, giving an overall Down syndrome detection rate of 94.7% for our first-trimester Down syndrome screening programme. This was an acceptable detection rate according to international standards[1,9]. Regarding the false-negative case, the known risk of fetal Down syndrome is 1 in 770. The corresponding fetal NT images were retrieved and reviewed by our MFM specialists. Both the image quality and the measurements were assessed to be acceptable. The quality of the fetal NT measurements in our centre, assessed by the measures of central tendency and dispersion, was also acceptable.

We believe that these favourable results were achieved by providing appropriate training and auditing of operators. Midwives with a background obstetric ultrasound experience were selected for fetal NT measurement training. This approach can reduce the learning curve and time required for training sonographers. Regular auditing by providing individualised feedback to sonographers was recommended to ensure consistent and improved performance[10]. In our unit, this was achieved by 3-monthly feedback of fetal NT MoM and SD log values to our sonographers. Image of fetal NT measurements was assessed during the first 6 months of individual fetal NT reporting to ensure strict adherence to standard ultrasound techniques.

It is generally accepted that quality assurance for medical processes improves as the numbers performed by an individual increase[3]. Quality assurance activity targeting fetal NT MoM may be inaccurate or impossible if too few NT measurements are performed by individual sonographers. However, our midwive sonographers performed 386 to 1387 fetal NT scans in the study period (Table 1). Fetal NT MoM values could therefore be used to assess individual performance.

Although there were significant differences in some of the pregnancy characteristics encountered by the two groups of operators, the differences were small clinically. These small differences were probably related to midwives scanning low-risk pregnancies, while doctors scanned high- and low-risk pregnancies.

There were no statistically significant differences in the NT MoM values obtained between using the two different ultrasound machines. We postulated that the measurement techniques and ultrasound settings were more important for determination of valid and reliable fetal NT measurements than the model of the ultrasound machine. In the literature, comparison of fetal NT measurements obtained by the two ultrasound machines has not been reported.

The performance of trained midwives in measuring fetal NT was comparable to that of trained doctors. Our department will continue to train and develop midwives to provide fetal NT measurements, and audit their performance on a regular basis. Any fetal NT exceeding 3.5 mm or the suspicion of abnormalities warrants patient referral for further assessment. Although non-invasive prenatal diagnosis (NIPD)[11,12] is available to patients, for the following reasons our department nevertheless offers first-trimester combined screening. Thus, first-trimester screening offers an opportunity to ensure fetus viability, correct dating, and diagnosis of multiple pregnancies. Second, fetal abnormalities can be determined by scanning at this gestational age[13-19], as shown in our study. Third, if a thickened NT is evident during the first trimester, detailed echocardiography of the fetal heart and morphology scans are necessary in second trimester so as to exclude major congenital heart disease and genetic syndromes[20]. Fourth, NIPD is not recommended for primary screening, as its cost-effectiveness has yet to be determined[11].

There are different approaches to auditing first-trimester Down syndrome screening and fetal NT measurements. Individualised feedback to sonographers regarding their measures of central tendency (median MoM) and dispersion (SD log MoM) are recommended to ensure consistent and improved performance[21]. Notably, 40 to 60% of NT measurements should be above the

median value for gestational age. Stored fetal NT images could be reviewed to ensure strict adherence to fetal NT measurement protocols. In our department, fetal NT images obtained during the first 6 months of independent fetal NT measurement are reviewed. In our current study therefore, we aimed to compare the performance of doctors and midwives based on mean fetal NT MoM values.

One limitation of this study was that we compared the performance in NT measurements in doctors and midwives as a group. Performance of individual sonographers was audited by other means, with results given to individuals and were not used in this study. In this study moreover, fetal NT images were also not assessed. Thus, auditing activity has to be reviewed together with other quality assurance processes. A head-on comparison with doctors and midwives performing NT measurement for the same patient might reveal inter-observer variations, but the study size for such a study design would be much smaller. Second, the sample size and methodology were not adequate to compare NT measurements between the two ultrasound machines. Theoretically, comparisons should be made using different ultrasound machines for measurement of fetal NT for the same patient, but this was not clinically practical. It would also be of interest to compare differences in NT MoM measurements between doctors and midwives after controlling for the ultrasound machines being used. However, this was not performed as the majority of scans using the Medison V20 machine were performed by doctors.

Conclusion

It seems that the performance of trained midwives in measuring fetal NT is comparable to that of trained doctors. Our preliminary results did not show a significant difference in fetal NT MoM values obtained using the two ultrasound machines with standardised settings. Regular audits should be continued to monitor the performances in NT measurements by both doctors and midwives.

Declaration

No conflicts of interests were declared by authors.

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