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Early second trimester transvaginal ultrasound anomaly scan does not cause adverse perinatal outcome☆

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ABSTRACT

Objective: During an early second-trimester transvaginal ultrasound anomaly scan, pressure is applied to the uterus, and the fetus is often rotated manually to allow scanning of its various organs. This study was designed to determine if performing a transvaginal ultrasound anomaly scan during the early second trimester of pregnancy is associated with adverse perinatal outcome or cord entanglement.
Methods: During the 4.5 year study period we prospectively collected cases of routine ultrasound scans at 14–17 weeks gestation performed as anomaly screening, together with perinatal outcome. The study population consisted of 164 women who underwent a transvaginal approach, and the control population consisted of 224 women in which a transabdominal approach was used. Data on perinatal parameters was collected from delivery charts from the four local hospitals.
Results: There were more operative deliveries (vaginal or Cesarean) in the transvaginal scan group (32% vs. 23%, $p = 0.05$). However, on multiple logistic regression analysis vaginal scans were not associated with increased operative delivery rates with an adjusted odds ratio of 1.47 and a 95% confidence interval of 0.85–2.54. There were no other clinically significant differences in perinatal outcomes, or in cord entanglement.
Conclusions: Transvaginal ultrasound anomaly scan conducted in the early second trimester of pregnancy is a safe procedure for the fetus.

1. Introduction

It is common practice in Israel to perform an early second trimester ultrasound anomaly scan at 14 through 17 weeks gestation. Many operators and patients prefer an abdominal approach. However, not infrequently, a vaginal scan is necessary due to poor image resolution, maternal obesity, abdominal wall scarring or difficult fetal position [1–3].

When performing the vaginal ultrasound anomaly scan in the early second trimester of pregnancy, the examiner must, in many cases, apply gentle pressure to the uterus, to actively rotate the fetus bi-manually in order to facilitate visualization of the fetal organs from different viewpoints and to achieve better planes of imaging. The examiner conducts this by rotating the transducer in combination with applying light manual abdominal pressure. In contrast, during an abdominal examination there is no need to rotate the fetus. The transducer is moved and rotated over the pregnant woman's abdomen to obtain different angles of vision of the fetal organs.

The aim of this study was to determine whether a transvaginal ultrasound anomaly scan during the early second trimester, which frequently entails applying pressure to the uterus as well as active bi-manual rotation of the fetus, is safe, or is associated with adverse perinatal outcome or cord entanglement, when compared to an abdominal non-vaginal ultrasound anomaly scan at the same stage of pregnancy.

We have found no previous publications which address this issue.

2. Patients and methods

During 4 one month slots, between January 2005 and June 2009, we prospectively collected and evaluated routine ultrasound anatomy scans performed at 14 through 17 weeks gestation of singleton pregnancies at the ultrasound unit of the Department of Obstetrics and Gynecology in Shaare Zedek Medical Center and at the authors' (RB, OS) ultrasound clinic in Jerusalem. The sole consideration during the entire study for selecting abdominal or vaginal scanning was the need for adequate image resolution. The primary outcome studied was umbilical cord entanglement around the fetus's neck or other organs. Secondary adverse outcomes studied were: premature birth, fetal distress prior to or during the birth, placental abruption, thick meconium at birth, the need for instrumental delivery or a Cesarean section due

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Table 1
Patient characteristics.

Patient characteristics		Abdominal approach	Vaginal approach	p value
Number of women		224	164	
Age	Average	30.2 ± 4.9	29.7 ± 5.2	0.35
	Range	18–42	17–44	
People at home		3.4 ± 1.5	3.35 ± 1.6	0.58
Average rooms at home		3.9 ± 1.35	3.7 ± 1.1	0.16
Average people to rooms ratio		0.926	0.923	0.95
Education	Average years of schooling	15.2 ± 2.5	14.7 ± 2.5	**0.027**
	Academic education, n (%)	162 (74)	108 (67.5)	0.21
Average parity		1.4 ± 1.5	1.3 ± 1.5	0.47
Nulliparas, n (%)		74 (33)	67 (40.9)	0.135
Average BMI[a]		23.1 ± 3.4	25.2 ± 5.55	<**0.001**
Previous Cesarean sections, n (%)		24 (10.7)	20 (12.2)	0.75

± SD.
Bold values indicate significance at p value ≤0.05.
[a] BMI = Body Mass Index (kg/m^2).

to fetal distress, dystocia or fetal malpresentation, low Apgar scores, low birth weight and hospitalization in a neonatal intensive care unit.

We obtained the perinatal outcomes from all four hospitals in Jerusalem: Shaare Zedek Medical Center, Hadassah Ein Kerem Medical Center, Hadassah Mount Scopus Medical Center and Bikur Holim Medical Center. All ultrasound examinations were performed by one of four experienced examiners, each with over ten years of experience. Institutional review board approval, and informed consent were obtained for this prospective study. Standard ultrasonography was performed according to the guidelines of the Israel Society of Obstetrics and Gynecology criteria [4]. Patients who underwent both abdominal and vaginal ultrasound scans were included in the vaginal group. All examinations initially used the abdominal approach; the vaginal approach was used when indicated due to poor imaging quality, often due to maternal obesity or fetal position. Three cases from the vaginal group, and four from the abdominal group were excluded due to major anomalies. We estimated that with 200 patients in each group, the study would have 80% power, with an alpha value of 0.05, to detect a between-group difference in the main outcome variable of cord entanglement, of at least 10 percentage points, assuming 15% incidence in the general population [5–8]. As there were more cases in the abdominal group, recalculating when the groups had reached 160 and 220 cases respectively, left the power unchanged. Statistical analyses were performed using SPSS (released 2008, SPSS Statistics for Windows, Version 17.0, Chicago: SPSS Inc.). Statistical tests included χ^2, Fisher's exact test, t-test and logistic regression model. Results were presented as mean ± standard deviation (SD). Results at $p \leq 0.05$ were considered significant.

3. Results

Of 451 patients entered into the study, outcome data were available for 388, and these comprised the two study groups. Delivery charts of the remaining 63 patients could not be found, the majority probably having delivered in a different city. There were no significant differences in patient characteristics between those lost to follow-up in the vaginal group (19 cases) and the abdominal group (41 cases). Of the 388 pregnant women, 224 examinations were performed exclusively from an abdominal approach and 164 from a vaginal or combined approach. Demographic data for the two study groups is shown in Table 1. A significantly increased average BMI was noted in the vaginal scan group (25.2 ± 5.55) as compared with women from the abdominal scan group (23.1 ± 3.4) ($p < 0.001$). The cases were roughly evenly distributed between the four examiners.

While performing the transvaginal ultrasound scan the examiners subjectively assessed the amount of rotation they caused the fetus. There was either no rotation during the exam (1.2% of the cases), minimal rotation (20.7%), a moderate amount of rotation (42.7%), or a great amount of rotation (19.5%). In 15.8% of the cases this parameter was not noted.

For the primary study result, the incidence of umbilical cord entanglement, there was no difference between the groups (Table 2). There were statistically marginally more operative deliveries (vaginal or Cesarean) in the vaginal ultrasound group as compared to the abdominal ultrasound group ($p = 0.05$), and more low 1 min Apgar scores <7 ($p = 0.049$) in the abdominal ultrasound group. On comparing the incidence of operative delivery for indications possibly related to fetal rotation, fetal distress, dystocia or malpresentation, no differences were found between the groups. There was one case of placental abruption in each group, both cases in term pregnancies. There were no further differences between the groups concerning the other secondary study results.

Four of the patient characteristics examined (Table 3) were significantly associated with operative delivery (abdominal or vaginal). On multivariate logistic regression analysis, three of these variables: previous Cesarean section, parity and maternal age, were significantly associated with operative deliveries. The ultrasound approach did not impact this outcome (Table 4).

4. Discussion

The safety of transvaginal early second trimester anomaly scan has not been previously established with respect to perinatal outcome. Considering the trend in several leading centers to lower the gestational age

Table 2
Perinatal outcome by sonographic approach.

Adverse perinatal outcome	Abdominal approach (N = 224) N (%)	Vaginal approach (N = 164)	p value
Umbilical cord entanglement around fetus's neck or other organs	42 (18.8)	20 (12.2)	0.09
Umbilical cord entanglement more than once around the fetus's neck or other organs	7 (3.2)	5 (3.0)	1
Fetal distress	40 (17.9)	34 (20.7)	0.51
Instrumental delivery or Cesarean section	52 (23.2)	53 (32.3)	**0.05**
Instrumental delivery or Cesarean section due to fetal distress or dystocia	27 (12)	27 (16.5)	0.24
Instrumental delivery or Cesarean section due to fetal distress, dystocia or malpresentation	31 (13.8)	33 (20.1)	0.1
Cesarean section	36 (16.1)	39 (23.8)	0.07
Fetal malpresentation	4 (1.8)	6 (3.6)	0.33
Premature birth < 37 weeks	8 (3.6)	6 (3.7)	1
1 min Apgar score ≤ 7	9 (4)	1 (0.6)	**0.049**
5 min Apgar score ≤ 7	3 (1.3)	0 (0)	0.27
Thick meconium at birth	7 (3.8)	3 (2.8)	0.75
Admission neonatal intensive care unit	8 (4.5)	4 (3.6)	1
Birth weight < 10th percentile by sex and birth week	13 (5.9)	11 (6.8)	0.83
Any adverse perinatal outcome	97 (43.3)	65 (39.6)	0.53

Bold values indicate significance at p value ≤0.05.