Original Article

Evaluation of Fetal and Maternal Outcomes in Chorion Villus Sampling (CVS)

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Abstract

Background: Chorionic villus sampling (CVS) is one of the invasive diagnostic methods used to diagnose chromosomal, genetic, and metabolic diseases in the embryonic period. The use of this method is associated with maternal and fetal consequences, the most serious of which is abortion. Therefore, the present study was conducted to investigate the incidence of these consequences and the factors affecting the incidence of abortion.

Materials and Methods: A cross-sectional study was performed on 98 pregnant women with CVS indications. Maternal and fetal outcomes including abortion, vaginal bleeding, subchorionic hematoma, premature rupture of membrane (PROM), chorioamnionitis, preterm delivery, limb abnormality, fetal growth retardation, and preeclampsia were recorded.

Results: The results of the present study showed that the incidence of fetal outcomes including fetal growth failure, premature rupture of membranes, abortion, and limb abnormalities was 4.1%, 7.1%, 3.1%, and 1%, and the incidence of maternal outcomes including preterm delivery, subchorionic hematoma, preeclampsia, and hemorrhage was 14.3%, 3.1%, 6.1%, and 10.2%, respectively. In addition, a decrease in free BHCG and an increase in NT were significantly associated with the occurrence of abortion (OR: 0.11 and 4.25, respectively, P value < 0.05).

Conclusion: It should be noted that due to a long time between placental sampling and the occurrence of vaginal bleeding, premature rupture of membrane, and preterm delivery, it seems that placental sampling has no effect. In addition, only a decrease in free BHCG or an increase in NT significantly increased the chance of miscarriage.

Keywords: Abortion, chorionic villus sampling, chromosomal abnormalities, preeclampsia, pregnancy outcome

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Introduction

Early detection of some inherited fetal diseases by various methods such as chorionic villus sampling (CVS) through trans-abdominal and trans-cervical approaches is an accepted procedure across the world[1] since medical abortion prevents the birth of sick babies, which will promote the health of the community. This knowledge provides patients with the opportunity to seek counseling for obstetric management.[2] On the other hand, if the results are normal and the fetus is healthy, parental anxiety will also decrease.[3] Some of the indications for this test include diagnosis of chromosomal, genetic, and metabolic disorders following positive screening tests or positive family history, high maternal age, and sonographic findings.[4,5] Since this invasive diagnostic

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method still plays an important role in assessing fetal health. Therefore, by using medical guidelines regarding prenatal diagnosis tests, unnecessary invasive tests can be reduced in the future and the complication of abortion can be avoided to the extent.[6]

In addition to its benefits, CVS is associated with complications such as fetal death, rupture of membranes, vaginal bleeding, and chorioamnionitis.[7-10] Although several studies reported a risk of less than 1% for embryo loss, this can be the most serious complication of CVS.[9,11,12] Therefore, considering the risk of fetal loss and other possible risks, it seems that it is necessary to evaluate and identify the risk factors associated with the increased chance of complications of this invasive diagnostic test in pregnancy.[13] In this regard, many factors have been proposed as the possible risk factors for these complications, including maternal age, gestational age, placental position, twin pregnancy, fibroid, the number of needles, and the CVS method (trans-abdominal or trans-cervical).[9,10,14] Several studies have compared different invasive diagnostic methods such as CVS, amniocentesis, etc.[3,6,9,15] However, a small number of studies have investigated maternal and fetal outcomes and their determinants in Iran. Therefore, the present study was conducted to evaluate maternal and fetal outcomes and the risk factors associated with the most serious complications.

Materials and Methods

A cross-sectional study was conducted on all pregnant women presenting to Beheshti Hospital from March 2016 to March 2017 that met the following criteria: having a positive pregnancy screening test for the first time or having a child with inherited diseases, carrying pathological genes, and gestational age 11–14 weeks. About 150 eligible pregnant women were enrolled in the study using the census method.

The protocol of the study was approved by the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1399.703) and written consent was obtained from all participants. Maternal age, gestational age, number of deliveries, and initial screening results (including beta human chorionic gonadotropin (BHCG), nuchal translucency (NT), and pregnancy-associated plasma protein A (PAPPA)), and the number of needles used were recorded in a checklist. Then, chorionic villus sampling (CVS) was performed for all patients under ultrasound guidance. Two perinatologists performed CVS.

For CVS, after performing an ultrasound and examining the placenta, the first sterile prep and drep of the placenta were done. Lidocaine 2% was used for local anesthesia in the desired area on the abdomen. Then, under high-resolution ultrasound guidance (Affinity 70 Phillips), vacuum suctioning of the placental villi was done using spinal needle no. 18 with a trans-abdominal approach. The samples were placed in normal saline and sent to a genetics laboratory. Thirty patients with positive results for chromosomal disease (common trisomy or other aneuploidy anomalies) were excluded from the study according to genetic test results. Twenty-two patients were excluded due to uncooperativeness. Ninety-eight patients were monitored during pregnancy to investigate the maternal and fetal complications. The patients were followed up monthly and their history, ultrasound results, lab tests, and records were reviewed. Maternal and fetal complications including miscarriage, vaginal bleeding, chorionic hematoma, chorioamnionitis, premature rupture of the membrane (PROM), preterm delivery, fetal growth failure, limb abnormalities, preeclampsia, and the number of needles used were recorded. Finally, the collected data were analyzed using the SPSS software ver. 26 (IBM Corp., 2012, Armonk, NY, USA). Data are presented as mean ± standard deviation (SD) or frequency (percentage). Logistic regression was used to evaluate the factors associated with the increased chance of abortion caused by CVS. The significance level was set at 0.05 for all test results.

Results

In the present study, 98 pregnant women with a gestational age of 11 to 13 weeks and 6 days that had positive pregnancy screening results for the first time, had a child with inherited diseases or carried pathological genes underwent CVS. The mean age of the subjects was 32.16 ± 3.39 years and their mean gestational age was 12.85 ± 1.02 weeks. In addition, 58.2% of them were nulliparous and 41.8% were multiparous women. According to the initial screening, the mean BHCG, NT, and PAPPA were 1.98 ± 1.40 ng/ml, 2.25 ± 1.34 mm, and 0.82 ± 0.77 IU/I, respectively [Table 1].

Maternal outcomes included abortion (one month from CVS) in 3.1% of the cases, which did not occur within one week after sampling in any of the cases. In addition, premature rupture of membranes was detected in seven cases (7.1%), which occurred 4 months after CVS in all cases. In addition, fetal growth failure and limb abnormalities were seen in 4.1% and 1% of the cases, respectively. Ten cases (10.1%) had vaginal

Table 1: Basic characteristics of pregnant women

Variables	*n* (%) or Mean±SD
Maternal age; year	32.16±3.39
Gestational age; week	12.85±1.02
Parity	
Nulliparous	57 (58.2%)
Parous	41 (41.8%)
Needle insertion	
Once	95 (96.9%)
Twice	3 (3.1%)
Initial screening	
Free B HCG; mom	1.98±1.40
PAPP-A; mom	0.82±0.77
NT; mm	2.25±1.34

NT=Nuchal Translucency, BHCG=Beta Human chorionic gonadotropin, PAPP-A=pregnancy-associated plasma protein A. Chi-square Test)

bleeding, which occurred within one month of CVS in 4.1% and after one month of CVS in 6.1%. In addition, preterm delivery was found in 14 cases (14.3%), which occurred 2–4 months after CVS (27 weeks) in 1% and more than 4 months after CVS in 13.3%. In addition, the incidence of preeclampsia and the subchorionic hematoma was 6.1% and 3.1%, respectively [Table 2].

Given that the most important complications are fetal death and abortion, the present study found that a decrease in free BHCG and an increase in NT values were associated with an increase in the chance of abortion. Although increasing maternal age, gestational age, and parity count reduced the chance of miscarriage, these correlations were not significant (*P* value > 0.05) [Table 3]. Using the needle more than once (twice) did not have any significant effects on increasing the chance of abortions.

Discussion

The results of the present study showed that the most common fetal complications of CVS were premature rupture of membranes and FGR with incidence rates of 7.1% and 4.1%, respectively. The most common maternal outcomes were preterm delivery and vaginal bleeding with an incidence of more than 10%. By contrast, there were only 3 cases of subchorionic hematoma (maternal outcome) and 1 case of limb deformity as the rarest complications in this study. There was no case of chorioamnionitis. Similarly, chorioamnionitis; in the conducted studies by Sistani and Sirikotiakel was reported as a rare complication in 308 and 185 patients, respectively,[16,17] in which no cases of embryonic membrane rupture were reported. The results of the present study were similar to two studies in which embryonic membrane rupture was not reported within 4 months after CVS.

Table 2: Maternal and fetal consequences

Fetal and maternal Consequences		*n* (%)
Fetal Consequences	Abortion	3 (3.1%)
	Premature Rupture of Membranes	7 (7.1%)
	Less than 1 month after CVS	0 (0%)
	1-2 months after CVS	0 (0%)
	2-4 months after CVS	0 (0%)
	Rather than 4 months after CVS	7 (7.1%)
	Fetal Growth Restriction	4 (4.1%)
	Limb Anomaly	1 (1.1%)
Maternal consequences	Vaginal bleeding	10 (10.2%)
	Less than 1 month after CVS	4 (4.1%)
	Rather than 1 month after CVS	6 (6.1%)
	Subchorionic hematoma	3 (3.1%)
	Preterm Labor	14 (14.3%)
	2-4 months after CVS	1 (1.1%)
	Rather than 4 months after CVS	13 (13.2%)
	Preeclampsia	6 (6.1%)
	Chorioamnionitis	0 (0%)

Chisquare Test

Table 3: Factors affecting the incidence of abortion

Factors	Odd ratio	95% CI	*P*
BHCG	0.11	0.019-0.647	0.015
NT	4.25	1.01-17.94	0.041
Needle insertion	1.05	0.91-3.74	0.076
Maternal age	0.90	0.65-1.26	0.539
Gestational age	0.692	0.21-2.22	0.534
Parity	0.686	0.06-7.85	0.763

Logistic regression Test

In Martins's AT study, a total number of 1523 women with a singleton pregnancy did a CVS, The risk of abortion in the CVS group was 3.2%).[5] The result of the present study was similar to this study, which the rate of abortion (one month from CVS) in 3.1% of the cases.

The incidence of vaginal bleeding following CVS in 50 cases was 4%,[16] which is much lower compared to the present study.

The incidence of preeclampsia in Grobman *et al*.'s[8] study on 150 patients; was 3.3 percent. An observational study also reported an increased risk of preeclampsia in 412 women who underwent CVS women due to placental villus sampling and placental manipulation.[18] The incidence of preeclampsia following CVS was 6% in the present study.

A meta-analysis study found that the incidence of severe preeclampsia in 1532 patients was 4.4% in the CVS group and 8% in the control group.[19] In another study, the presence of subchorionic bleeding detected by ultrasound following CVS increased the risk of miscarriage, IUGR (Intra uterine growth retardation).[20] In the present study, the sub-chorionic hematoma was seen in three cases of which two cases developed placental abruption and bleeding, and finally abortion; both of these cases had very high NT values) 5–6 mm).

The fetal death due to infection following CVS in the first trimester of pregnancy chorionic villus sampling on 1409 patients was 1.68%.[13] It has been reported that trans-cervical CVS (TC-CVS) is theoretically associated with a risk of infection.[21] Although this hypothesis has not been proven in large studies, the present study also confirmed this finding since CVS was performed using the trans-abdominal method (TA-CVS) and no case of chorioamnionitis was observed in this study.

There was no increase in limb reduction defects, prematurity, low birth weight, fetal and neonatal mortality, and fetal distress in the chorionic villus sampling group.[11,22]

In a large study, 16 randomized studies, with a total of 33,555 women reported a higher incidence of congenital anomalies, including talipes (4.7% versus 2.7%; compared to the control group.[21] This complication is one of the rarest complications in the mentioned studies. There was no increase in limb reduction defects, prematurity, low birth weight, fetal and neonatal mortality, and fetal distress in the chorionic villus sampling group in the two studies.[11,22] One

of the cases developed club foot deformity in the present study. Due to sampling after 11 weeks gestation and the involvement of other factors, this anomaly does not seem to be related to placental sampling. Since all placental sampling procedures are performed by highly skilled perinatologists using the trans-abdominal method after 10 weeks gestation in recent years, no CVS-related limb abnormalities have been reported.

In addition, according to the results of the shahbazian study on 308 cases, the most common premature complication of CVS is heavy bleeding, which leads to miscarriage.[17] However, in several studies following CVS before 24 weeks gestation was associated with a fetal mortality rate of 1.5–4% in some studies.[12,16,23] Compared to other studies, the incidence of abortion was 3.1% in the present study. The results of this study showed that the determinants of the increase in the chance of abortion were a reduction in free BHCG and an increase in the NT value. Given that the sampling indication was positive for the first three pregnancy screening samples and no cases of abortion were found in any of the individuals sampled due to pathological carrier genes, it seems that the cause of abortion could be undiagnosed fetal malformations. Therefore, this invasive diagnostic method is highly dependent on the performer's skill; hence, mastery over ultrasound-guided methods and specialized training is required before and after performing CVS. In this regard, the results of the present study showed that due to the very little use of the second needle, the number of times a needle was used for sampling did not have a significant effect on the rate of abortion. Nonetheless, several studies found that using two or more needles had a significant effect on abortion.[24,25] In one study with a comparison of 234 trans abdominal CVS (TA-CVS) and 99 trans cervical CVS (TC_CVS) cases, the incidence of abortion in trans abdominal CVS was lower than that of transcervical CVS, 2.3% versus 1.3%).[26] Also, the Gil study on 3613 patients in the CVS group showed that the incidence of miscarriage in the CVS group was 2.1%.[14]

This indicates that the type of CVS method could not be assessed adequately because of incomplete karyotype data in most studies, and may be a determinant of complications.[21]

Maternal or gestational age and parity did not play a significant role in the incidence of abortion as the most serious complication of CVS. Similarly, Niromanesh *et al*. found that maternal age, gestational age at the procedure, placental position, and previous history of abortion did not play a significant role in the incidence of abortion following CVS. Among these factors, the only effective factor in the occurrence of abortion was the number of needles in the CVS method.[23] Odibo *et al.* also reported similar results[24] while some other studies reported opposite findings.[25,26] In fact, the use of the second needle has not been considered a factor in increasing the risk of complications. In one study, the incidence of abortion was lower in the TA-CVS method compared to the TC-CVS method,[27] suggesting that the type of CVS procedure can also be a determinant of complications. Maruotti *et al*.[28] reported that the odds ratio of preeclampsia, severe preeclampsia, and gestational hypertension did not increase significantly with the CVS procedure. In the present study, no relationship was found between the affective factors of CVS and complications such as limb abnormalities, preeclampsia, bleeding, etc., were not reported following CVS. Therefore, according to the results of the present study as well as other studies, placental sampling does not appear to have a significant effect on important pregnancy outcomes such as abortion, limb abnormalities, chorioamnionitis, premature rupture of membrane, preeclampsia, and preterm delivery.

Study limitation

Due to the small sample size and the low percentage of maternal and fetal outcomes, it was not possible to assess the factors affecting all of these outcomes, which could be one of the limitations of the study. In addition, this method was not compared with other invasive diagnostic methods such as amniocentesis, which could be considered another limitation. One of the strengths of this prospective study was performing CVS for all pregnant women by two skilled specialists in this center. Therefore, the skill of the surgeons, the technique, and the equipment used did not have a confounding effect on the observed complications. In the present study, the specialists that performed CVS were very experienced, and therefore this procedure was associated with very few complications such as miscarriage, chorioamnionitis, preterm delivery, and premature rupture of fetal membranes. Nowadays, due to the increasing number of CVS cases, further studies are required to identify the predisposing factors for fetal death as well as late and early fetal and maternal outcomes due to invasive diagnostic methods (such as CVS, amniocentesis, and other methods). Because identifying and controlling the related factors helps to prevent these complications to a large extent

Conclusion

According to the results of the present study, the most common fetal and maternal consequences of CVS were vaginal bleeding, premature rupture of the membrane, and preterm delivery more than 4 months after delivery. It is important to note that in the present study, there was a large time interval between placental sampling and the onset of premature rupture of membranes and preterm delivery. Therefore, placental sampling at 11-14 weeks' gestation does not appear to have any effects on these outcomes. Hence, it seems that placental sampling between 11 weeks and 13 weeks, and 6 days does not affect maternal and fetal outcomes. In addition, only a decrease in free BHCG and an increase in the NT value caused a significant increase in the chance of miscarriage.

Ethical considerations

The Isfahan University of Medical Sciences Ethics Committee (code: IR.MUI.MED.REC.1399.703) approved this study. Informed consent was obtained from all participants.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity.

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Conflicts of interest

There are no conflicts of interest.

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