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Evaluation of prenatal invasive testing complications in a tertiary care centre

Üçüncü basamak merkezde prenatal invaziv test komplikasyonlarının değerlendirilmesi

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ABSTRACT

Aim: Invasive tests such as amniocentesis or chorionic villus sampling (CVS) are associated with an increased risk of miscarriage, testing should be done with caution in pregnancies considered to be at high risk for aneuploidies and other genetic disorders. The aim of our study is to present the complications that develop after invasive prenatal tests such as amniocentesis, cordocentesis and chorionic villus sampling.

Materials and Methods: A retrospective observational study was conducted covering a period of 3 years and 1 month, involving 282 pregnant women at high risk of genetic disorders who underwent invasive prenatal testing such as chorionic villus sampling, amniocentesis, or cordocentesis.

Results: A statistically significant difference was found in at least one group in terms of gestational age at delivery, birth weight, current week and pregnancy risk among amniocentesis, cvs and cordocentesis groups ($p<0.05$). The average birth weight of the amniocentesis group (3099.04 ± 688.21) was found to be higher than the cvs group (2172.42 ± 1551.06). The risk of screening test for amniocentesis (0.0038±0.0063) and cordocentesis groups (0.001±0.0023) was found to be higher than the cvs group (0.0058±0.0061) The rate of USG anomaly in the cordocentesis group (73.2%) was found to be different from the Amniocentesis group (42.8%) and cvs group (12.1%). The rate of termination was found to be higher in the CVS (33.3%) and cordocentesis (31.7%) groups compared to the amniocentesis (4.3%) group.

Conclusion: Complication rates including bleeding, redness at the wound site, fetal bradycardia, amniotic fluid leakage, chorioamnionitis, miscarriage were similar among group.

Keywords: Amniosentesis, chorionic villus sampling, cordosentesis, invasive prenatal testing, complications

ÖZ

Amaç: Amniyosentez veya koryon villus örneklemesi (CVS) gibi invaziv testler artmış düşük riski ile ilişkilidir, anöploidiler ve diğer genetik bozukluklar açısından yüksek riskli olduğu düşünülen gebeliklerde test dikkatli yapılmalıdır. Çalışmamızın amacı, amniyosentez, kordosentez ve koryon villus örneklemesi gibi invaziv prenatal testlerden sonra gelişen komplikasyonları sunmaktır.

Gereçler ve Yöntem: Yüksek genetik bozukluk riski taşıyan ve koryon villus örneklemesi, amniyosentez veya kordosentez gibi invaziv prenatal testler uygulanan 282 gebeyi kapsayan ve 3 yıl 1 aylık bir süreyi kapsayan retrospektif gözlemsel bir çalışma gerçekleştirilmiştir.

Bulgular: Amniyosentez, cvs ve kordosentez grupları arasında doğumdaki gebelik yaşı, doğum ağırlığı, mevcut hafta ve gebelik riski açısından en az bir grupta istatistiksel olarak anlamlı fark bulundu ($p<0.05$). Amniyosentez grubunun ortalama doğum ağırlığı (3099,04±688,21) CVS grubundan (2172,42±1551,06) daha yüksek bulunmuştur. CVS, amniyosentez (0,0038±0,0063) ve kordosentez gruplarında (0,001±0,0023) tarama testi riski cvs (0,0058±0,0061) grubuna göre daha yüksek bulunmuştur. Kordosentez grubundaki USG anomali oranı (%73,2), amniyosentez grubu (%42,8) ve CVS grubundan (%12,1) farklı bulunmuştur. Terminasyon oranı CVS (%33,3) ve kordosentez (%31,7) gruplarında amniyosentez (%4,3) grubuna kıyasla daha yüksek bulunmuştur.

Tartışma: Kanama, yara yerinde kızarıklık, fetal bradikardi, amniyon membran rüptürü, koryoamniyonit, düşük gibi komplikasyon oranları gruplar arasında benzer olarak bulunmuştur.

Anahtar Kelimeler: Amniyosentez, koryon villus örneklemesi, kordosentez, invaziv prenatal testler, komplikasyon

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INTRODUCTION

Amniocentesis is a medical procedure used to collect fetal cells from the amniotic fluid in order to identify chromosomal abnormalities in the fetus. The procedure is typically performed after sixteen weeks, with the assistance of ultrasound, this prenatal diagnostic technique can be beneficial for families when there are concerns about genetic disorders (1,2). Prenatal diagnosis is obtained through amniocentesis (3,4). It allows for early detection of any chromosomal issues, enabling parents and healthcare providers to prepare for the birth and plan for the child's future health and care needs. Certain indications may lead a healthcare provider to recommend amniocentesis. These include maternal age over 35 years, a family history of genetic conditions, previous pregnancies with abnormalities, or ultrasound findings indicating potential issues with the fetus. The procedure may also benefit women who test positive for genetic abnormalities in first or second trimester screening tests (1,5,6) .

While amniocentesis can provide crucial information, it is an invasive procedure that carries risks for both the mother and fetus. Therefore, it is vital for healthcare professionals to offer thorough counseling about the reasons for the procedure, its risks, benefits, and limitations. Although the risks are generally small, any potential complications should be discussed openly with expectant mothers. (7,8). Over recent years, there has been a notable rise in the number of pregnant women undergoing invasive prenatal diagnostic procedures, such as amniocentesis and chorionic villus sampling. Advances in these techniques now allow for earlier scheduling of procedures, which can lead to quicker diagnoses (9). A primary concern about these invasive methods is the risk of miscarriage and fetal loss (10). There has also been interest in understanding any potential fetal complications resulting from these procedures. (11). While studies on maternal complications address the psychological impact of prenatal tests, other complications after invasive prenatal tests have not been adequately investigated (12).

Research indicates that there may be connections between amniocentesis and issues such as prenatal bleeding, placental abruption, and leakage of amniotic fluid. (12,13). The likelihood of such complications appears to rise when amniocentesis is performed in the early stages of pregnancy (14). Similar risks have been associated with chorionic villus sampling as well. However, some studies have reported no significant increase in pregnancy complications (15,16). The interpretation of these findings requires careful consideration, as there are limited reports addressing maternal complications, and many studies lack proper control groups (17).

The purpose of this study is to determine whether amniocentesis and chorionic villus sampling, when routinely performed for pregnancies with low-risk indications, lead to an increased risk of maternal complications. This includes issues like bleeding during pregnancy, placental abruption, complications related to the amniotic membranes, complications affecting labor, and birth-related issues compared to women who have not undergone these procedures.

MATERIAL AND METHODS

This was a retrospective observational study conducted on patients who underwent prenatal invasive testing between July 2020 and July 2023. After ethical approval (22/11/2023- ESH/GOEK 2023/63R) was obtained to conduct this study, all pregnant women at high risk for genetic disorders who underwent invasive prenatal testing such as chorionic villus sampling, amniocentesis, or cordocentesis were included in this study. A total of 282 consecutive women were selected from the database according to our inclusion and exclusion criteria. The invasive procedures were conducted by a single operator (Z.B) at a single medical centre.

• Inclusion criteria: Patients receiving diagnostic intervention due to positive biochemical/ultrasonographic/both screening or positive history of genetic disorder in previous child or known mutation, with or without family history of genetic syndrome. Genetic diagnostic testing was offered to patients with a combined risk >1/1000.

• Exclusion Criteria: Patients were excluded from the study if they underwent interventions for reasons other than those specified, such as fetal reduction, fetal blood transfusions, fetal therapy. Additionally, those who opted out of invasive testing were not included. A single practitioner conducted a comprehensive ultrasound examination, followed by a detailed consultation with the patient and their family. During this consultation, the necessity, risks, and potential complications of prenatal invasive tests were discussed, as well as alternative options, including their relative benefits and drawbacks. Informed consent was obtained in writing from all participants prior to the procedure. All interventions were performed using a transabdominal approach under sterile conditions. A 22G spinal needle was used for amniocentesis, while a 20G spinal needle was utilized for chorionic villus sampling and cordocentesis, with ultrasound guidance applied through a free-hand technique by the same individual. Following the procedures, all patients received prophylactic oral antibiotics and progesterone support, with anti-D injections administered as needed. The ultrasound examination and invasive procedures were conducted

using a transabdominal curved transducer, either 3.5–5 MHz or 2–9 MHz, on a GE Voluson E8 system.

This retrospective study gathered data from departmental records regarding maternal age, reasons for the invasive tests, family history of genetic syndromes, ultrasound findings from the current examination, and results of the tests. Additionally, information on both early and late complications related to the procedures—such as miscarriage, infections, amniotic fluid leakage, fetal injury, and fetal loss were also recorded and analyzed using SPSS version 22.0.

RESULTS

A statistically significant difference was found in at least one group in terms of birth week, birth weight, current week and pregnancy risk between amniocentesis, cvs and cordocentesis groups ($p<0.05$). In the pairwise comparisons made;

The mean of the amniocentesis group at birth week (37.5±3.72) was found to be higher than the cvs group (29.58±12.31). Summary of some of the categoric and continuous variables among groups were summarized in Table 1 and 2.

The average birth weight of the amniocentesis group (3099.04±688.21) was found to be higher than the cvs group (2172.42±1551.06).

All groups were found to be different in terms of the current week. The highest mean was found in the cordocentesis group (25.98±2.65), followed by the amniocentesis group (19.59±2.62) and the lowest mean in the cvs group (12.55±0.51) (Table 3).

The risk of screening test for amniocentesis (0.0038±0.0063) and cordocentesis groups (0.001±0.0023) was found to be higher than the cvs group (0.0058±0.0061). A higher biochemical risk does not necessarily correspond to an increased likelihood of chromosomal abnormalities. In our study, only 19% of fetuses with a nuchal

Table 1. Invasive test groups and complications rates

	Groups	n	%
Invasive test	Amniocentesis	208	73.8%
	CVS	33	11.7%
	Cordocentesis	41	14.5%
Indication	Increased risk at screening test	74	26.2%
	Fetal structural anomaly	123	43.6%
	Fetal structural anomaly and increased risk for screening test	85	30.1%
Bleeding	No	280	99.3%
	Yes	2	0.7%
Hyperemia	No	276	97.9%
	Yes	6	2.1%
Bradycardia	No	279	98.9%
	Yes	3	1.1%
Amnion leakage	No	281	99.6%
	Yes	1	0.4%
Chorioamnionitis	No	281	99.6%
	Yes	1	0.4%
Miscarriage	No	281	99.6%
	Yes	1	0.4%
Termination	No	249	88.3%
	Yes	33	11.7%
Route of delivery	Vd	184	65.2%
	Cs	98	34.8%
Fetal sex	Girl	185	65.6%
	Boy	97	34.4%

Table 2. Demographic data of patients

	n	Mean	SS	Min	Max
Gestational age at delivery (weeks)	282	36.16	6.3	12	41
	282	2903.97	973.54	20	4230
Age (years)	282	29.53	5.71	17	45
Height (cm)	282	162.28	5.48	150	178
Weight (kg)	282	69.65	13.15	45	113
Gravidity	282	2.28	1.51	1	12
Parity	282	1.02	1.11	0	8
Weeks	282	19.69	4.22	12	32
Risk	282	0.0036	0.006	0.0001	0.0476
BMI (kg/m2)	282	26.44	4.74	16.26	42.44

Table 3. Pregnancy and delivery data of the three invasive test groups

	Intervention	n	Mean	SS	Mean Rank	p
Gestational age at delivery (weeks)	Amniocentesis	208	37.5	3.72	150.58	**0.001**
	Cvs	33	29.58	12.31	96.74	
	Cordocentesis	41	34.66	6.21	131.44	
Birth weight (grams)	Amniocentesis	208	3099.04	688.21	151.5	**0.002**
	Cvs	33	2172.42	1551.06	106.55	
	Cordocentesis	41	2503.17	1215.94	118.89	
Age (years)	Amniocentesis	208	29.89	5.62	145.72	0.302
	Cvs	33	29.06	6.09	135.03	
	Cordocentesis	41	28.07	5.7	125.29	
Height (cm)	Amniocentesis	208	162.27	5.77	141.83	0.775
	Cvs	33	161.88	5.44	133.15	
	Cordocentesis	41	162.66	3.9	146.54	
Weight (kg)	Amniocentesis	208	70.09	13.58	143.34	0.492
	Cvs	33	66.39	11.46	125.7	
	Cordocentesis	41	70.02	12.12	144.88	
Bmi	Amniocentesis	208	26.6	4.82	143.23	0.66
	Cvs	33	25.39	4.45	129.36	
	Cordocentesis	41	26.49	4.6	142.5	
Gravide	Amniocentesis	208	2.26	1.44	142.18	0.875
	Cvs	33	2.36	2.03	134.98	
	Cordocentesis	41	2.32	1.46	143.32	
Parite	Amniocentesis	208	1.03	1.1	142.91	0.542
	Cvs	33	0.85	1	127.8	
	Cordocentesis	41	1.15	1.28	145.39	
Weeks	Amniocentesis	208	19.59	2.62	138.72	**<0.001**
	Cvs	33	12.55	0.51	17	
	Amniocentesis	41	25.98	2.65	255.79	
Risk	Cvs	208	0.0038	0.0063	139.54	**<0.001**
	Cordocentesis	33	0.0058	0.0061	197	
	Amniocentesis	41	0.001	0.0023	0.0002	0.0006

translucency measurement above the 95th percentile were found to have chromosomal abnormalities. Similarly, 21% of fetuses in the study that presented with an absent nasal bone were diagnosed with trisomy 21.

A proportional difference was observed in at least one group of the Amniocentesis, Cvs and Cordocentesis groups according to the indication for invasive testing ($p<0.001$). In the pairwise comparison, no difference was seen in the rate of combined test risk in the three

Table 4. Differences between the three groups according to fetal invasive tests

	Category	Amniocentesis		Cvs		Cordocentesis		p
		n	%	n	%	n	%	
Indication	High risk for combined test	57	27,4%[a]	11	33,3%[a]	6	14,6%[a]	**<0,001**
	Fetal anomaly	89	42,8%[a]	4	12,1%[b]	30	73,2%[c]	
	Both	62	29,8%[a]	18	54,5%[b]	5	12,2%[a]	
Bleeding	No	207	99,5%	32	97,0%	41	100,0%	0,241
	Yes	1	0,5%	1	3,0%	0	0,0%	
Hyperemia at scar	No	204	98,1%	32	97,0%	40	97,6%	0,651
	Yes	4	1,9%	1	3,0%	1	2,4%	
Bradycardia	No	207	99,5%	33	100,0%	39	95,1%	0,093
	Yes	1	0,5%	0	0,0%	2	4,9%	
Amnion leakage	No	207	99,5%	33	100,0%	41	100,0%	0,999
	Yes	1	0,5%	0	0,0%	0	0,0%	
Choriamnionitis	No	207	99,5%	33	100,0%	41	100,0%	0,999
	Yes	1	0,5%	0	0,0%	0	0,0%	
Miscarriage	No	207	99,5%	33	100,0%	41	100,0%	0,999
	Yes	1	0,5%	0	0,0%	0	0,0%	
Termination	No	199	95,7%	22	66,7%	28	68,3%	**<0,001**
	Yes	9	4,3%[a]	11	33,3%[b]	13	31,7%[b]	
Route of delivery	Vd	118	56,7%	30	90,9%	36	87,8%	**<0,001**
	Cs	90	43,3%[a]	3	9,1%[b]	5	12,2%[b]	
Sex	Girl	135	64,9%	22	66,7%	28	68,3%	0,908
	Boy	73	35,1%	11	33,3%	13	31,7%	

groups. All rates were found to be different in those performed for USG anomaly. The rate of USG anomaly in the Cordocentesis group (73.2%) was found to be different from the Amniocentesis group (42.8%) and CVS group (12.1%). The rate of those performed for both risk and USG findings in the CVS group (54.5%) was found to be higher than in the Amniocentesis (29.2%) and Cordocentesis groups (12.2%).

The rate of termination was found to be higher in the CVS (33.3%) and cardocentesis (31.7%) groups compared to the Amniocentesis (4.3%) group. Distribution of complications following three different procedures was presented in Table 4.

DISCUSSION

In this study, we aimed to analyze the complications that arise after invasive prenatal procedures such as amniocentesis, cordocentesis, and chorionic villus sampling. We discovered that the rate of pregnancy termination was significantly higher in the CVS group (33.3%) and the cordocentesis group (31.7%) compared to the amniocentesis group, which had a termination rate of only 4.3%. Additionally, the rate of cesarean sections was higher in the amniocentesis group (43.3%) compared to the cordocentesis (12.2%) and CVS groups (9.1%).

Amniocentesis involves piercing the membranes, whereas chorionic villus sampling (CVS) does not. This distinction could help explain why there is a greater risk of complications related to the amniotic sac following amniocentesis, while such risks are less associated with CVS. Research has found a notable connection between amniocentesis and the leakage of amniotic fluid after the procedure (18). These studies documented pregnancy complications from the moment the procedure was performed until delivery. One particular study conducted in Canada found that early amniocentesis was linked to a higher risk of fetal loss and the development of talipes equinovarus (19). The association between invasive procedures and unusual birth outcomes has not been extensively documented, with the exception of a British study that noted an increased incidence of dysfunctional labor following amniocentesis (20). The

higher incidence of instrumental vaginal deliveries observed in the amniocentesis group, along with a similar increase in the chorionic villus sampling group, aligns with the findings of abnormal birth types linked to invasive procedures. However, prior studies have not indicated any association between these invasive techniques and the frequency of instrumental deliveries (21).

In a systematic meta-analysis, Akolekar indicated that the risk of miscarriage related to the procedures of amniocentesis and chorionic villus sampling was significantly lower than what had been previously reported, with figures of 0.11% for amniocentesis and 0.22% for CVS (22). Guidelines for invasive procedures indicate that the risks associated with amniocentesis include fetal loss (ranging from 0.1% to 1%), amniotic fluid leakage (between 1% and 2%), and chorioamnionitis (less than 1%). After undergoing amniocentesis, the likelihood of amniotic fluid leakage remains elevated for up to 24 weeks, although spontaneous closure of the membranes is frequently observed (23). Factors such as less experience, multiple interventions, bloody amniotic fluid, and the presence of fetal abnormalities can elevate the risk of fetal loss. According to the literature, the complication rates associated with chorionic villus sampling vary, showing fetal loss rates between 0.2% and 2%, and about 10% for vaginal bleeding. Additionally, the risk of fetal loss increases with repeated needle insertions and if the procedure is performed at a gestational age of less than 10 weeks.

The incidence of fetal loss following transcervical chorionic villus sampling (CVS) is noted to be elevated, with rates reported around 2.5%. A previous study indicated that a single operator conducted over 145 procedures annually, totaling 433 procedures over three years, without experiencing any major complications. During the subsequent eight weeks post-amniocentesis, CVS, or cordocentesis, no complications including amniotic fluid leakage, chorioamnionitis, or fetal loss were reported in any cases. Among the CVS procedures where the placenta was situated, only three instances of vaginal bleeding (0.7%) were documented, a figure significantly lower than what the literature typically indicates. The success rate for obtaining samples was 100% in a single session and 99.3% in a single attempt. Overall, a lower complication rate was observed in their study compared to existing literature, likely attributed to the fact that all procedures were performed by a single fetal medicine consultant with 20 years of extensive experience, adhering to stringent protocols for pre- and post-procedure care. Such a minimal complication rate is typically achievable only after navigating a considerable learning curve (24). According to the literature, the rates of failure to culture amniocyte or trophoblastic cells following amniocentesis and chorionic villus sampling (CVS) are reported to be 0.1% and 0.5% respectively. In a prior study, culture failure occurred in 2 cases (0.46%) of the total, both of which involved patients who underwent chorionic villus sampling for biochemical screening that was positive for trisomy 21, despite having normal fluorescence in situ hybridization (FISH) results. Notably, none of the patients required reoperation. (25)

A systematic review has revealed considerable variation in the rates of pregnancy loss and complications following both amniocentesis and chorionic villus sampling (CVS). For amniocentesis specifically, data on pregnancy loss within 14 days post-procedure indicated no significant variability, with a pooled loss rate of 0.6%. However, the risk of fetal loss tends to rise with longer follow-up periods, increasing from 0.6% within 14 days to 1.9% for overall pregnancy loss. While these percentages can be useful for general guidance, they do not account for the inherent background risk, which means they do not fully address the additional risks associated with the procedures. Notably, the baseline risk for women undergoing CVS will typically be higher than that for those undergoing amniocentesis, as amniocentesis is usually performed later in pregnancy, when the likelihood of spontaneous miscarriage is reduced. It seems reasonable to conclude that this distinction is a significant factor contributing to the elevated miscarriage rates observed in women who undergo CVS (26).

A review of the literature on amniocentesis included control groups to assess background risk. The pooled findings revealed a 25% relative increase in total pregnancy loss following amniocentesis and a 46% rise in pregnancy loss before 24 weeks of gestation. However, these results were notably heterogeneous, leading to wide confidence intervals that were not statistically significant. The absolute risk difference between the cases and controls was found to be comparable, indicating that the risk of pregnancy loss during the second trimester and overall fetal loss increases by approximately 0.6% after amniocentesis. Furthermore, the use of non-randomised control groups may introduce significant bias, as they typically do not allow for a direct comparison between the two groups (27). The significant differences observed in complication rates are surprising, especially considering that all studies were conducted under ultrasound guidance by well-trained personnel. The rates of amniocentesis procedures that required multiple needle insertions ranged from 0.2% (representing 9 out of 3,696 cases) to 2.8% (58 out of 2,068 cases) and 2.9% (7 out of 240 cases) (28).

In conclusion, cesarean sections was significantly higher in the amniocentesis group (43.3%) compared to the cordocentesis group (12.2%) and the chorionic villus sampling (CVS) group (9.1%). However, the complication rates including issues such as bleeding, redness at the wound site, bradycardia, amniotic fluid leakage,

chorioamnionitis, and miscarriage were found to be similar across all groups.

Ethics Committee Approval:
Ethical approval (22/11/2023- ESH/GOEK 2023/63R) was obtained to conduct this study.

Conflict of Interest
The authors declare no conflict of interest.

Author Contributions
Z.B., M.K., E.A.S. conceived the study. and G.Ş., K.S. searched the literature and collected the data. M.K., E.A.S. and G.Ş. performed the statistical analysis. Z.B., M.K., K.S. drafted the manuscript. Z.B., G.Ş., K.S. reviewed the manuscript. Both authors contributed to editorial changes in the manuscript. Both authors have read and approved the final paper. Both authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

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