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June 2012

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Recommended Citation

Munim, S., Ismail, H. (2012). Pregnancy loss rate following amniocentesis. *Journal of the Pakistan Medical Association*, 62(6), 545-547.
Available at: https://ecommons.aku.edu/pakistan_fhs_mc_women_childhealth_obstet_gynaecol/4

Pregnancy loss rate following amniocentesis

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Abstract

Objective: To determine pregnancy loss rate following amniocentesis in a mainstream urban healthcare centre.

Methods: We analysed cases of all pregnant women who underwent Amniocentesis at the Foetal Medicine Unit of Aga Khan University Hospital, Karachi, during 2001 to 2010. Cases of unknown pregnancy outcome were excluded, and after the process of consent, the final study population was 228 patients. Two operators performed the procedure using 22 G needle.

Results: The mean age of women in the study was 32±6 years. The commonest indication of the procedure was a previous baby with Down's Syndrome. Majority 197 (86.6%) cases had a normal karyotype. Down's syndrome was 14 (6.1%). Regarding the outcome of pregnancies, it was normal in 173 (77.3%) cases while 2 (0.8%) intrauterine deaths were reported, one of which was within two weeks of the procedure. The number of pregnancy termination was 27 (11.7%). There was one miscarriage which means the pregnancy loss rate in the study population was 0.4%.

Conclusion: In order to have good quality control, healthcare audits are essential on both short-term and long-term basis.

Keywords: Amniocentesis, Chromosomal abnormality, pregnancy loss (JPMA 62: 545; 2012).

Introduction

Amniocentesis is the most commonly performed invasive procedure in Foetal Medicine. It is performed from 16 weeks of pregnancy. The primary purpose of the procedure remains chromosomal analysis, the results of which are then used in the counselling of couples and discussion about the options available for pregnancies complicated with chromosomal abnormalities.

The counselling of women for an invasive procedure is based on her likelihood of having a baby with chromosomal abnormality versus the risk of procedure-related miscarriage. The risk of miscarriage was reported to be between 0.5-1%.¹⁻³ This figure is based on the results of some case controlled studies^{1,2} and a single randomised controlled trial done on low-risk women population in the 1980s.³

The technique of Amniocentesis has come a long way since its introduction in the 1970s. Now almost all such procedures are performed under continuous ultrasound guidance and, therefore, the risk of miscarriage is even less than that reported in the literature.^{1,2} As the expertise of this procedure has improved considerably, an increasing number of women above the age of 35 are opting for this procedure. In several countries routine serum screening or Nuchal Translucency screening is in place,⁴ which identifies high-risk women who need invasive testing. This approach has resulted in reduced number of invasive procedures.⁵

Although Amniocentesis is a commonly performed procedure, but it is important to ensure that standards are being followed. The aim of this study was to determine the risk of miscarriage with Amniocentesis and to monitor the performance of this service at our unit.

Patients and Methods

The observational cohort study used data of all Amniocentesis cases performed during 2001 to 2010 at the Foetal Medicine Unit of AKUH. We included all women who underwent the procedure during this time. However, given the geographical diversity of the patients attending the unit, it was difficult to follow up all pregnancy outcomes. We excluded cases with unknown pregnancy outcomes and those who were not willing to participate in the study.

The study was approved by the Ethical Review Committee of the Aga Khan University Hospital. As part of the policy, every referred woman to the FMU is requested to sign consent to allow the use of their information with confidentiality. Additional consent, however, was obtained prior to the procedure. In addition to the demographic characteristics, we noted the main indications for the procedure, which included: Advanced maternal age; Positive maternal serum screening; Previous baby affected by Down's Syndrome; Previous baby with other chromosomal abnormality; Suspicious ultrasound findings in the current pregnancy; Family history of chromosomal abnormalities; Triple test results; and any other observation.

All patients who were referred to our unit underwent an ultrasound scan prior to the procedure. Initially we used Toshiba Nemio machine (Tokyo, Japan) and later on Medison Accuvix (Seoul, Korea). Following the ultrasound, they were counselled about the procedure and due consent was obtained. As a routine we checked the rhesus status.

Two trained operators performed Amniocentesis in our unit, using 20 G spinal needle. The first 1 ml was discarded to minimise the contamination with the mother's blood cells and then 16 mls were removed and sent for Fluorescence In Situ Hybridisation (FISH) and Karyotype. During the procedure a local anaesthetic was also given.

The patients were counselled about the complications of the procedure and given information leaflet and contact numbers prior to discharge. They were also encouraged to keep us informed about the outcome of the pregnancy.

For statistical analysis, descriptive measures were used to analyze the categorical data. Frequencies and percentages were used for result of amniocentesis.

Results

A total number of 228 patients were part of the study. The mean age of women in the study was 32±6 years. Out of the study subjects, 89 (38.8%) were above 35 years of age.

Over half of the Amniocentesis procedures were performed between 16 and 18 weeks of gestation (n=129; 56.8%). Indications of the procedures performed in our unit were separately noted (Table-1).

There was culture failure in three of the initial samples. The procedure failed in one case where it had to be repeated. The rate of miscarriage was 0.4% (n=1) (Table-2). The study cohort was followed up till delivery and outcomes were recorded, showing 173 (77.3%) livebirths. There were 2 (0.8%) cases of IUD post Amniocentesis, one of which was within two weeks of the procedure, accounting for 0.4% of the pregnancy loss rate in the study cohort. In the other case the pregnancy was complicated with multiple anomalies and resulted in foetal demise at 26

Table-1: Indication of Amniocentesis.

Indication	Number	(%)
Advanced maternal age	43	18.9
Previous Down's baby	68	29.8
Increased Nuchal Tranlucency	4	1.8
Previous history of structural abnormal baby	13	5.7
Triple test positive	34	14.9
Family history of congenital abnormalities	6	2.6
Abnormality in present pregnancy	23	10.1
Previous chromosomal abnormal baby	22	9.6
Thalasemia	15	6.6
Total	228	100.0

Table-2: Results of Amniocentesis.

Test result	Frequency	Percent%
Normal karyotyping	197	86.4
Trisomy 21	14	6.1
Trisomy 18	5	2.6
Thalasaemia major	6	2.3
Thalasaemia minor	1	0.4
Technically failed	4	1.8
Triploidy	1	0.4
Total	228	100.0

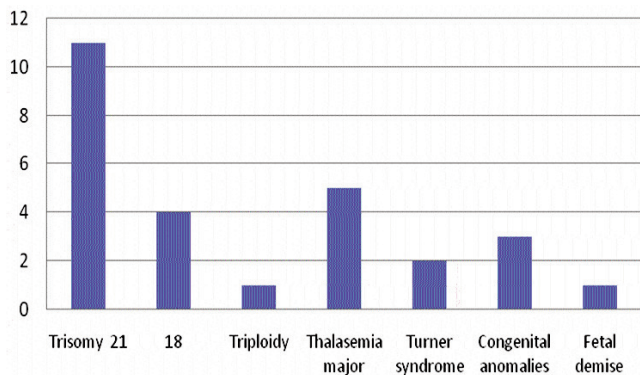


Figure: Details of termination of pregnancy.

weeks. Among the study subjects, 27 (11.7%) cases underwent termination of pregnancy (Figure).

Discussion

Amniocentesis is the most common invasive procedure performed in foetal medicine. It was introduced in the 1970s.^{1,2} The main purpose to undertake this test is for the determination of foetal karyotype. Apart from the diagnosis of chromosomal abnormalities, it can be used in some genetic abnormalities. In our study, the majority underwent Amniocentesis for the determination of karyotype. The procedure is commonly performed between 16-20 weeks. In our study over half of the women (56.8%) underwent Amniocentesis before 18 weeks of gestation.

The procedure-related risk of Amniocentesis has been extensively studied by many researchers. The report of the British Medical Research Council is one of the earliest one where the miscarriage rate was 0.9%.¹ The only randomised controlled trial was that reported by Tabor et.al in 1970s which reported it to be 0.7%.³ Other studies published have also reported the risk to be 0.5-1%.⁶⁻¹⁰ In our study, the risk was 0.4%.

The miscarriage risk also depends on the gestational age at which the procedure is performed and is much higher if the procedure is performed before 14 weeks. None of the patients at our unit underwent early Amniocentesis.

The risk of Amniocentesis-related miscarriage is over and above the background risk of miscarriage. The risk of spontaneous miscarriage quoted is around 1%. Therefore, the risk of procedure-related miscarriage is not more than the background risk in our study.

The other common complications reported with this procedure are the risk of bleeding, abdominal cramping and

leaking. The risk of leaking following the procedure has been reported to be 1%.⁸ However, there was no case complicated with leaking in our study. Similarly, there was no case of Talipes.

The majority of chromosomal abnormalities reported in the pre-natal diagnosis are of Trisomy 21, 18 or 13 and sex chromosome aneuploidies.⁶ Therefore, the predominant reason for Amniocentesis is to rule out these abnormalities, in particular Down's Syndrome. Eighty percent of women in our study population underwent Amniocentesis for the same.

Three of the cases had culture failure in our initial cases, accounting for 1.3%. The success rate of the specimens is consistent with that reported by others.^{7,11} The results of the study are consistent with the other reported literature and our complication rate is also within acceptable limits.

Conclusion

In order to have good quality control, such audits need to be conducted regularly. Unfortunately a vast majority of patients coming to our unit happen to be either from other cities or from other hospitals in the city. As such, following the outcome remains a great challenge.

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