Instruments & Methods

REDUCTION IN AMNIOCENTESIS RISKS USING A REAL-TIME NEEDLE GUIDE PROCEDURE

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Rates of complications associated with a second trimester genetic amniocentesis were studied in 918 patients, and complete infant follow-up was obtained. In 903 singleton pregnancies and 15 twin gestations, the procedure was performed under continuous sector scanning guidance through an attached needle guide. Eight fetal deaths in the 903 cases occurred at less than 28 weeks after amniocentesis (0.89%), none within two weeks after the procedure. Only one fluid was visibly blood contaminated. Comparisons are made with other series from the literature. (*Obstet Gynecol 65:751, 1985*)

In the early experience with second trimester genetic amniocentesis, large controlled studies documented the safety of this procedure.[1-3] A later uncontrolled study confirmed this in 3000 amniocenteses.[4] With the increasing use of ultrasound direction[5] or continuous ultrasound guidance,[6,7] the known complications associated with amniocentesis seem to have decreased, although this is not the finding in all series.[8]

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The rate of fetal loss attributable to amniocentesis has never been clear but has been presumed to be about 0.5% or less with experienced operators.[9] Adequate documentation still does not exist for a measurable decrease in this rate. This is a difficult aspect of any study design because of the problems of truly representative control groups as well as the differences in background rates of loss in different series and patient populations. The authors report a refinement in amniocentesis technique that has resulted in a further decrease in amniocentesis complications, probably including the rate of fetal loss.

Materials and Methods

Between September 1981 and September 1983, 918 women underwent an ultrasound-guided second trimester genetic amniocentesis at the University of Iowa Hospitals and Clinics. These procedures were performed with the aid of a needle guide* attached to the sector scanning head. A 22-gauge needle routinely was used for amniocentesis. Fifteen sets of twins were included in the present series. For these latter procedures, indigo carmine was injected into the first aspirated sac using the technique of Elias and associates.[10] The ultrasound units used were the ADR 2140 Sector Scanner and ADR 4000 S/L.

The lucite guide shown in Figure 1 was soaked for 15 minutes in Cidex (activated dialdehyde) between uses. Before soaking, the gel was removed from the sites for needle insertion. Under supervision of the operator, an ultrasound technician performed the initial ultrasound examination and, with assistance from the clinic nurse coordinator, sterilized and wrapped the sector scanner. The sector head was first cleansed with soap and water followed by Betadine (povidone–iodine), and then was wrapped with a sterile drape. The guide was rinsed with sterile saline before attachment. Approximately five minutes elapsed from completion of the initial ultrasound examination to completion of the amniocentesis. Figures 2 and 3 show the sterilized equipment on the maternal abdomen and an amniocentesis through this needle guide. Figure 4 demonstrates the visualization afforded.

Seventy-five percent of patients were referred because of maternal age greater than or equal to 35 at the time of delivery. In couples not at risk for a fetus with a neural tube defect, the availability of α-fetoprotein (AFP) as a screening procedure for these defects was discussed, and 96% of such couples elected this evaluation. Maternal serum AFP and amniotic fluid AFP were both obtained.

*CIVCO Medical Instruments Co., Inc., Kalona, IA.

0029-7844/85/$3.30

Figure 1. The lower portion of this figure shows the part of the lucite guide that has sites for inserting a 22-, 20-, or 18-gauge needle.

Patient information, indication for the procedure, complications, and fetal outcome were compiled and computerized. The rate of infant follow-up has been 100%, as ascertained from the patients and referring physicians. Follow-up data were obtained via telephone in the uncommon event that neither patient nor physician provided written follow-up. Further information was obtained if any untoward pregnancy outcome resulted, such as premature birth, stillbirth, or a neonate born with malformations.

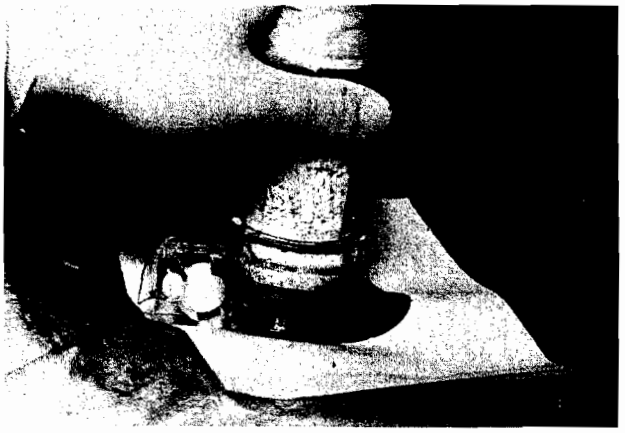

Figure 2. The attached guide is shown. The left side houses a detachable, rotating insert for use in in utero transfusions or related procedures.

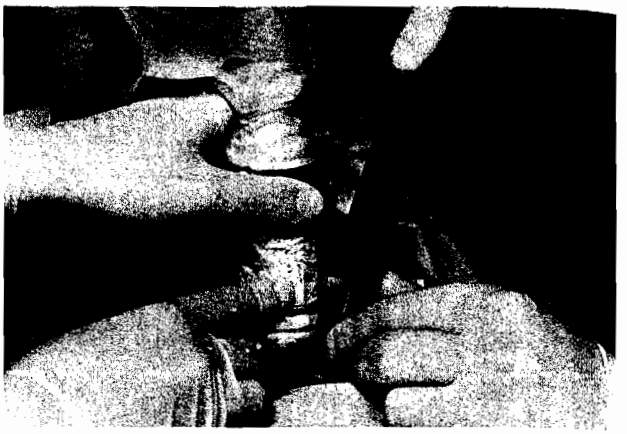

Figure 3. Withdrawal of amniotic fluid is demonstrated.

Results

In addition to the 918 patients on whom amniocentesis was performed, six women were found to have fetal deaths before the anticipated procedure. No amniocenteses were therefore performed in these cases. In five viable singleton pregnancies, an empty second gestational sac also was visualized. Green fluid was aspirated in four cases and brown fluid in 11 cases. For women referred because of maternal age indication, 2.2% had fetuses with chromosome abnormalities, not including balanced translocations. There were no errors encountered in the chromosome evaluations. No fetal neural tube defects were detected, and none were seen at birth. The expected incidence in Iowa is ap-

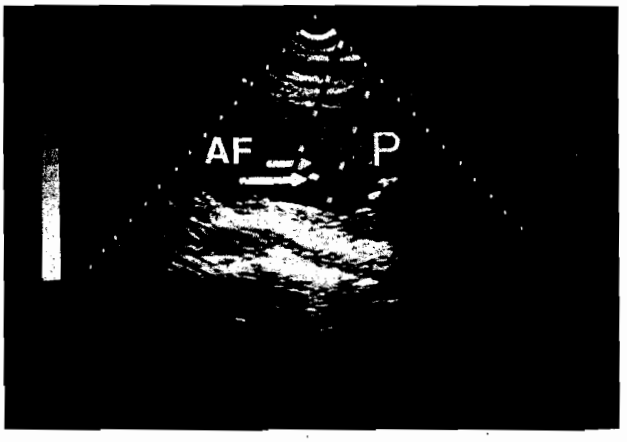

Figure 4. The needle enters the amniotic fluid (AF) at about a 17° angle and takes a path between the lines shown. These lines are drawn onto a template that attaches to the cathode ray tube. An anterior placenta (P) is shown. Arrows demonstrate needle tip, lower, and shaft.

proximately one per 1000.[11] Likewise, no fetal biochemical errors were detected. Congenital malformations were seen in 2.6% of offspring, and the average birth weight of infants greater than 28 weeks' gestation was 3460 g.

Table 1 details the complications in singleton pregnancies. Significantly, only one instance of blood-stained fluid was observed with the guide, and no cases of false-positive elevation of amniotic fluid AFP secondary to fetal blood contamination occurred. The cell culture failed in 0.2% of cases.

In most instances of failure to obtain fluid (1%) or need for multiple insertions (5.4%), the reason(s) was usually obvious when the guide was used. The most common reason was tenting of the fetal membranes, a known cause for amniocentesis failures.[12] Another common cause was uterine contraction, which occurs with almost every procedure. When the procedure is attempted close to the lateral uterine wall, the needle tip can be obstructed after a uterine contraction.

One infant, born with an enlarged, glaucomatous right eye and an opaque cornea, was diagnosed as having congenital angle-closure glaucoma. The ophthalmologists caring for the child believed this was compatible with needle perforation of the globe, although clear fluid was obtained after one insertion and the needle was not seen making contact with the fetus. Also, the right eyelid showed no evidence of trauma.

The shortest interval from amniocentesis to fetal death was two weeks (Table 2), this being a case involving one insertion and a posterior placenta. In no instance was there clinical evidence of amnionitis preceding the pregnancy loss. Two of those eight fetal deaths were associated with an elevated maternal serum AFP level.

In addition to the eight fetal deaths less than 28 weeks after amniocentesis, five other pregnancies were associated with fetal death. One was a 1200-g live-born male who died with multiple anomalies shortly after delivery at 29 weeks' gestation. Another was a 1336-g male infant of a poorly controlled diabetic mother who experienced an intrauterine fetal death at 28 weeks. A third loss occurred secondary to a placental abruption at 31 weeks' gestation, with delivery of a 1440-g stillborn female. Two other infants with no obvious anomalies were stillborn at 35 weeks' gestation and term, respectively. Thus, the total fetal death rate in the present group was 1.4% (13 of 903).

Clear fluid was aspirated from both sacs in 14 of the 15 twin gestations. In one case a separating membrane could not be visualized, and fluid was obtained from only one sac. Three sites of needle insertion far removed from the successful first tap yielded bluish fluid, although at delivery, a second sac was evident. The perinatal outcome was favorable for 29 of 30 infants, the exception being a trisomy 21 fetus who died in utero at about 32 weeks. In addition to this case of twin–twin chromosomal discordance, a second set also was encountered in which one twin had 47,XXY (Klinefelter).

Of 15 amniocentesis procedures associated with either green fluid (four) or brownish fluid (11), the fetal outcome was favorable at term or near term in 14 of these cases. The exception is the last case listed in Table 2.

RhoGAM was administered to all but one unsensitized Rh negative woman at risk for an Rh positive fetus. This patient elected not to have RhoGAM after discussing the rationale for its use and the theoretic, though unproved, fetal risks from this medication. There was also one case of maternal sensitization after amniocentesis in a woman who received RhoGAM but became sensitized to E antigen.

Table 1. Complications of Amniocentesis in 903 Singleton Pregnancies*

Complication	No. (%)
Pregnancy loss <28 wk	8 (0.89)
Blood-stained fluid	1 (0.1)
Need to repeat, unable to obtain fluid	9 (1)
Need to repeat, culture failure	2 (0.2)
Multiple insertions to obtain fluid	49 (5.4)
2 insertions	41
3 insertions	8
Conspicuous needle trauma	1†

* The average gestational age by fetal biparietal diameter at the time of the tap was 16.6 weeks. Of 117 cases in which the biparietal diameter was 15 weeks or less and the procedure attempted, clear fluid was aspirated through the guide in all cases with no instances for need to return because of inability to obtain fluid or culture failure.
† Still questionable at this time.

Table 2. Interval Between Amniocentesis and Fetal Death Less Than 28 Weeks

Tapped at (wk gestation)	Gestation lost (wk)	Comments
15.5	20	PROM
17.5	25	IUFD
15	20	
17	23	IUFD
16	19	
15.5	17.5	
16	23	Premature labor Elevated serum AFP
18	27	PROM—empty second sac Elevated maternal serum AFP Brownish fluid

IUFD = intrauterine fetal death; PROM = premature rupture of membranes; AFP = α-fetoprotein.

Discussion

Although a concurrent control group for the present study did not exist, a previous series from this institution reported an equivalent number of procedures in which the needle guide technique was not used.[13] One obstetrician (MV) also participated in that series as one of two operators. In 911 singleton pregnancies in the previous study from January 1977 to December 1980, the fetal death rate at less than 28 weeks after amniocentesis was 1.9% compared with 0.89% in the 903 singleton pregnancies in the present series. The 1.9% loss rate compares favorably with other series from the early 1980s.[14,15]

The total rate of fetal death in the current group in whom the guide was used for singleton pregnancies was 1.4%. If the 15 twin gestations are added, including the third trimester death of a trisomy 21 fetus, the total fetal loss rate is 1.5%. Three other US studies have specified total rates of fetal loss and the periods over which these losses occurred. The National Institute of Child Health and Human Development collaboration study reported a total fetal death rate of 3.5% after amniocentesis. In that series, the loss from weeks 15 to 29 was 2.8%.[1] Hill et al[15] reported a 3.03% rate of fetal loss in their series, of which 0.89% occurred in the first week after the procedure. Porreco et al[14] experienced 2.84% total losses, with a 2.07% loss rate occurring between the time of amniocentesis to 28 weeks.[14]

Most reports either do not address the incidence of bloody amniotic fluids obtained or, if cited, do not mention the possible relationship to subsequent fetal outcome. This may be related to the conclusion of the National Institute of Child Health and Human Development study that indicated that bloody amniotic fluid was not related to fetal loss. A large well-controlled study by Ron and colleagues[16] documents what seems intuitively would be the case: Bloody amniotic fluid caused by the procedure does significantly increase fetal loss. In that study, the controls with clear fluid had a rate of fetal loss of 1.7%, but the fetal loss rate was 6.6% when maternal blood contaminated the amniotic fluid and was 14.3% with fetal blood contamination. Bloody fluid also increases the incidence of culture failure[17] and is associated with increases in maternal serum AFP after the test.[18] The fetal death rate has been reported to be higher with an amniocentesis-induced rise in maternal serum AFP.[19–21]

The frequently reported increase in fetal loss rate after withdrawal of greenish or brownish fluid[4,13,22] was not observed, as only one in 15 cases with this finding was associated with a fetal loss in the present study. There is recent evidence that greenish fluid is not meconium but rather old blood.[23] Based on hemoglobin content, it would appear that a significant fraction of this can represent fetal blood.

The case of possible ocular trauma in a male fetus secondary to the procedure warrants further discussion. Uniocular blindness believed related to a second trimester amniocentesis has been reported by Merin and Beyth.[24] In their case, however, the first 2 mL of fluid were contaminated with fetal blood. Congenital glaucoma occurs in about one of 10,000 newborns and predominates in males with a ratio of about 3:1.[25]

With the visualization afforded by the described method, needle injury was not evident in any other case in which the guide was used, if indeed eye trauma did occur in the present case. A stable physical connection of the sector head with the guide has the advantage of maintaining the needle in the plane of the sector image (about 0.2 mm width), although with beveled needle tips, the needle occasionally deviates out of the scanning plane. Thus, fetal injury can potentially occur if the needle is advanced without its being constantly visualized. This requires the sonographer to make minor adjustments of the sector head in response to uterine dynamics, maternal breathing, and needle bending. This has been a relatively easy task to learn, and seems less capricious than attempting to track a needle not in the direct path of the scanning plane. In a recent study of continuous ultrasound visualization of the procedure without this physical connection, the needle was seen striking the fetus in 27 of 131 procedures.[26]

Improvements in amniocentesis technique such as reported herein will continue to be important. Many states are, or will soon begin, screening for fetal neural tube defects by means of maternal serum AFP testing. The risk/benefit ratio has been questioned for this screening. It has been calculated that the rate of intended fetal losses (elective abortions, assuming all fetuses with neural tube defects would be aborted) to unintended fetal losses (procedure-related) would be a ratio of about 4:1.[27] Nontraumatic amniocentesis procedures will be important in the acceptance of maternal serum AFP screening, and indeed to second trimester testing in general. An often-cited reason for a couple to decline amniocentesis is the low but definite risk of fetal loss.

In conclusion, the authors have reported a large series of midtrimester genetic amniocenteses in which continuous ultrasound guidance has been associated with the lowest rate of fetal death yet reported. This technique, or similar variants, would now seem appropriate for widespread use.

References

1. NICHHD National Registry for Amniocentesis Study Group. JAMA 236:1471, 1976

2. Simpson NE, Dallaire L, Miller JR, et al: Prenatal diagnosis of genetic disease in Canada: Report of a collaborative study. Can Med Assoc J 115:739, 1976
3. Galijaard H: European experience with prenatal diagnosis of congenital disease: A survey of 6121 cases. Cytogenet Cell Genet 16:453, 1976
4. Golbus MS, Loughman WD, Epstein CJ, et al: Prenatal genetic diagnosis in 3000 amniocenteses. N Engl J Med 300:157, 1979
5. Carpenter RJ, Hinkley CM, Carpenter AF: Midtrimester genetic amniocentesis: Use of ultrasound direction vs. blind needle insertion. J Reprod Med 28:35, 1983
6. Beracerraf BR, Frigoletto FD: Amniocentesis under continuous ultrasound guidance: A series of 232 cases. Obstet Gynecol 62:760, 1983
7. Defoot P, Thiery M: Amniocentesis with the use of continuous real-time echography: Experience with two hundred consecutive cases. Am J Obstet Gynecol 147:973, 1983
8. Nolan GH, Schmickel RD, Chantaratherakitti P, et al: The effect of ultrasonography on midtrimester genetic amniocentesis complications. Am J Obstet Gynecol 140:531, 1981
9. Milunsky A: Risk of amniocentesis for prenatal diagnosis. N Engl J Med 293:932, 1975
10. Elias S, Gerbie AB, Simpson JL, et al: Genetic amniocentesis in twin gestations. Am J Obstet Gynecol 138:169, 1980
11. Greenberg F, James LM, Oakley GP: Estimates of birth prevalence rates of spina bifida in the United States from computer-generated maps. Am J Obstet Gynecol 145:570, 1983
12. Platt LD, DeVore GR, Gimovsky ML: Failed amniocentesis: The role of membrane tenting. Am J Obstet Gynecol 144:479, 1982
13. Cruikshank DP, Varner MW, Cruikshank JE, et al: Midtrimester amniocentesis: An analysis of 923 cases with neonatal follow-up. Am J Obstet Gynecol 146:204, 1983
14. Porreco RP, Young PE, Resnick R, et al: Reproductive outcome following amniocentesis for genetic indications. Am J Obstet Gynecol 143:653, 1982
15. Hill J, Reindollar R, McDonough P: Ultrasonic placental localization in relation to spontaneous abortion. Prenatal Diagnosis 2:289, 1982
16. Ron M, Cohen T, Yaffe H, et al: The clinical significance of blood-contaminated midtrimester amniocentesis. Acta Obstet Gynecol Scand 61:43, 1982
17. Miskin M, Doran TA, Rudd N, et al: Use of ultrasound for placental localization in genetic amniocentesis. Obstet Gynecol 43:872, 1974
18. Dubin CF, Staisch KJ: Amniocentesis and fetal–maternal blood transfusion: A review of the literature. Obstet Gynecol Surv 37:272, 1982
19. Mennuti MT, DiGaetano A, McDonnell A, et al: Fetal-maternal bleeding associated with genetic amniocentesis: Real-time versus static ultrasound. Obstet Gynecol 62:26, 1983
20. Lele AS, Carmody PJ, Hurd ME, et al: Fetomaternal bleeding following diagnostic amniocentesis. Obstet Gynecol 60:60, 1982
21. Thomsen SG, Isager-Sally L, Lange AP, et al: Elevated maternal serum alpha-fetoprotein caused by midtrimester amniocentesis: A prognostic factor. Obstet Gynecol 62:297, 1983
22. King CR, Prescott G, Pernoll M: Significance of meconium in midtrimester diagnostic amniocentesis. Am J Obstet Gynecol 132:667, 1978
23. Hankins G, Rowe J, Quirk JG, et al: Significance of brown and/or green amniotic fluid at the time of second trimester genetic amniocentesis. Obstet Gynecol 64:353, 1984
24. Merin S, Beyth Y: Uniocular congenital blindness as a complication of midtrimester amniocentesis. Am J Ophthalmol 89:299, 1980
25. Kwitko ML: Congenital glaucoma: A clinical study. Can J Ophthalmol 2:91, 1967
26. McArdle CR, Cohen W, Nickerson C, et al: The use of ultrasound in evaluating problems and complications of genetic amniocentesis. J Clin Ultrasound 11:427, 1983
27. Council on Scientific Affairs, American Medical Association: Maternal Serum α-fetoprotein monitoring. JAMA 247:1478, 1982

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