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Three years' experience of using a 29-gauge atraumatic needle for amniocentesis

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Abstract

Aims: To quantify the procedure-related complication rate after using modified technique of amniocentesis with a 29-gauge (29-G) pencil-point needle.
Methods: This is a prospective, descriptive study of 316 amniocenteses that were performed by means of atraumatic 29-G pencil-point needle under ultrasound control.
Results: A total of 316 amniocenteses were observed through the postprocedural period. The median time needed to retrieve 15 mL of amniotic fluid was 4 min. A total of 19 pregnancies were terminated after genetic testing. No case was regarded as procedure-related fetal loss. No other complications were observed. Seventeen children were born before 37 completed weeks of gestation and five children had a birth weight <2000 g.
Conclusions: Amniocentesis with the 29-G atraumatic pencil-point needle seems to be a safe procedure with extremely low risk of complications and is a good alternative to the traditional 22-G Quincke needle.

Keywords: Amniocentesis; atraumatic 29-guage pencil-point needle; complications; outcome.

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Introduction

Since chromosome analysis after amniocentesis was introduced in the mid-1960s by Steele and Breg [13], it made the examination of unborn children for the chromosomal aberrations possible. Today, it is the most commonly performed invasive prenatal diagnostic procedure [16]. Although an invasive method, with total fetal loss rates between 1% and 0.06%, it seems to be a relatively safe technique, as shown by previous studies [6, 14, 16]. In addition, procedure-related complications after amniocentesis performed with needles of different diameters were explored [1, 5, 6, 8, 17]. Moreover, an eventually elevated risk of fetal loss was examined in association with transplacental needle insertion [3, 4], angle of puncture [5, 7], numerous punctures [9], fetal abnormalities [10], and experience and specialization of the operator (obstetrician-gynecologist or perinatologist) [2, 12].

Some findings showed that thinner needles could cause a relatively higher flow rate *in vitro* when saline solution, instead of amniotic fluid, is used [5]. Nevertheless, they found that flow rate through a created defect exponentially increases with the diameter of the defect.

The purpose of this prospective, observational study was to investigate the procedure-related complication rates after introducing the new microinvasive procedure with a 29-guage (29-G) atraumatic pencil-point needle.

Materials and methods

Study design

We carried out a prospective, observational descriptive study of 306 women with single pregnancy and five with twins who underwent amniocentesis between January 2008 and February 2011 at the Department of Obstetrics and Gynecology, University Medical Center, Mainz, Germany. Pregnancy outcome data were obtained from hospital records.

The study group included women aged between 20 and 44 years with at least 15+0 weeks of pregnancy referred to our hospital for second trimester amniocentesis.

Exclusion criteria were vaginal bleeding <2 days before the procedure, body mass index higher than 35, and the use of medication containing heparin or aspirin 12 h before procedure. Any complication, such as amniotic fluid leakage, vaginal bleeding, iatrogenic preterm premature rupture of membranes, etc. had to be thoroughly documented as selected to be the criteria of the safety of the procedure.

The protocol for the intervention and data collection was approved by the institutional review board. All the procedures were conducted according to the Helsinki Declaration. Informed consent was obtained from each of the women before intervention.

Materials

All the amniocenteses were performed with an atraumatic 29-G needle (0.34×103 mm) (Tchirikov® 29-G needle; HVM Medical GmbH, Rotenburg an der Fulda, Germany), instead of previously used 22-G needle (Somatex, Teltow, Germany) (∅ 0.7 mm). The needles are shown in Figure 1. The 23-G guide needle (0.6×38 mm) was used to introduce the 29-G needle into the myometrium to avoid bending. The tip of the 29-G needle can be visualized by ultrasound much better compared with the standard Quincke needle because of different construction and increased ultrasound reflection. This special tip could be seen as the "white star" on the monitor (Figure 2).

Protocol of amniocentesis

Every participant received an ultrasound examination by means of Phillips iU22 (Phillips Ultrasound, Bothell, WA, USA) or GE Voluson 730 Expert (GE Medical Systems, Kretztechnik GmbH & Co OHG, Zipf, Austria) to confirm the gestational age and location of the placenta. The women were informed about any possible risks of the procedure.

- Step 1: The skin was disinfected and sterile ultrasound gel (SONOGEL Vertriebs GmbH, Bad Camberg, Germany) was applied.
- Step 2: The site for percutaneous introduction of the needle was selected using free-hand technique under real-time ultrasound guidance.
- Step 3: Initially, a 23-G guide needle was inserted into the abdomen at a 45° angle (Figure 3A), until the tip of the needle passed through at least two-thirds of the myometrium. The perforation of the chorioamniotic membrane must be strictly avoided.
- Step 4: The guiding needle was fixed by the fourth and fifth fingers. Then, the atraumatic 29-G needle was rapidly inserted through the guide needle and chorioamniotic membrane into the amniotic cavity with an angle of 45° using the first and the second fingers (Figure 3B). A transplacental needle insertion was avoided.
- Step 5: An adapter with the syringe was connected to the needle. We used a 20-mL VacLok® syringe (Merit Medical Systems, South Jordan, UT, USA) attached to a 20-cm connecting line (NEO CARE Medical Products, Lüdenscheid, Germany) (Figure 3C). After disconnecting the adapter, both the 29-G needle and the 23-G guide needle were extracted. Ultrasound examination was performed immediately after the procedure and between 24 and 48 h after amniocentesis to examine fetal heart activity and detect any complication. Complications were seen as procedure related if within 7 days after amniocentesis.

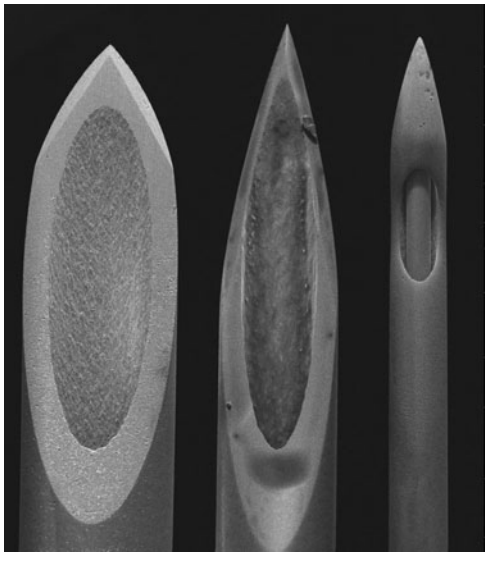

Figure 1 Tips of the different needles used for amniocentesis.
20- and 22-G Quincke needles from left to right and 29-G pencil-point needle.

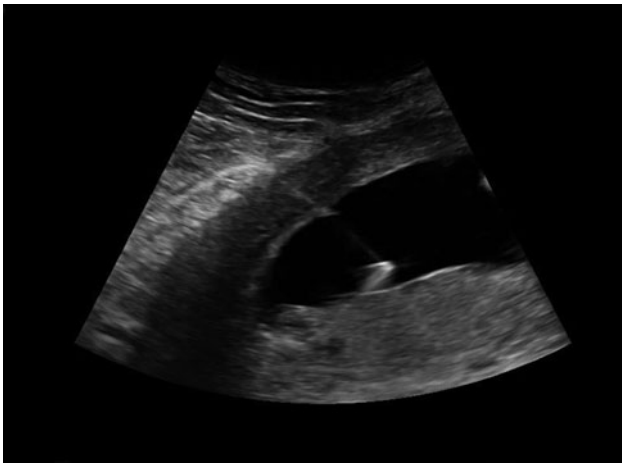

Figure 2 29-G needle in ultrasonography.
The tip of the 29-G pencil-point needle as a "white star" in the amniotic cavity.

Statistical analysis

For confirmatory analysis, a two-tailed non-parametric Mann-Whitney *U*-test was performed. Because two primary questions were analyzed, the significance level has to be corrected for multiple testing. This was done with the Bonferroni correction. The global significance level was 5%; thus, every single test was performed to the local level of 2.5% (SPSS Statistics 17.0; SPSS Inc., Chicago, IL, USA).

Results

A total of 311 patients who obtained the amniocentesis in our institution between January 2008 and February 2011 fulfilled the criteria for being punctured with the 29-G atraumatic pencil-point needle. Five of these women had twin pregnancy, which means that 316 amniocenteses were made at the term of our final analysis in March 2011.

Indications for invasive prenatal diagnostic procedure were as follows: advanced maternal age (n=222), positive family anamnesis (n=123), an elevated risk after first trimester screening (n=88) or an abnormal ultrasound finding (n=28), preexisting maternal diseases (n=16), and anxiety of the parents (n=3); often, patients had combined indications.

Women were between 20 and 44 years old (median, 37 years; interquartile range, 35.0–39.0 years). The median gestational age at amniocentesis was 16.0 weeks (interquartile range, 15.3–16.5 weeks). During the first year, the quantity of

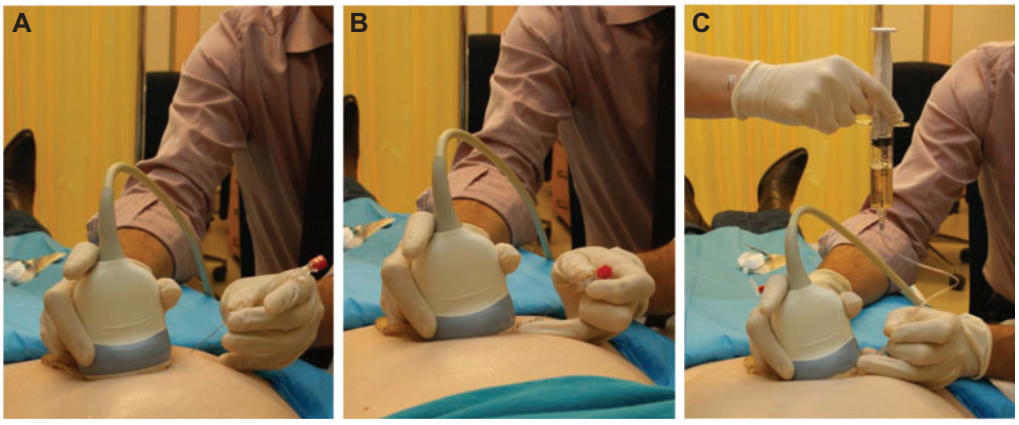

Figure 3 Puncture of the amniotic membrane with 29-G needle.
(A) Insertion of the 23-G guide needle. (B) Puncture of the amniotic membrane with the 29-G needle. (C) 29-G needle being connected to the VacLok® syringe.

the aspirated amniotic fluid ranged from 8 to 18 mL (median, 14.0 mL; interquartile range, 14.0–15.0 mL; n=154 cases). Since the introduction of the VacLok® syringe in December 2008, the quantity of the aspirated amniotic fluid (in cases 155–316) ranged from 10 to 18 mL (median, 15.0 mL; interquartile range, 15.0–16.0 mL; P<0.001). The median time needed to retrieve the amniotic fluid was 4.0 min (interquartile range, 4.0–5.0 min) for the normal syringe and 5.0 min (interquartile range, 4.0–5.0 min) for the VacLok® syringe, which was also significantly longer (P<0.001). The colors of the amniotic fluid and their distribution are shown in Table 1. The puncture was always successful. All women tolerated the minimally-invasive procedure extremely well. No complications were observed. One fetus had a bradycardia between 30 and 60 s, but it recovered soon after.

The aspirated amniotic fluid of all patients contained enough fetal cells that could be analyzed after culturing in a laboratory. In 24 of the 316 genetic examinations, the fetus had an abnormal karyotype. The different chromosomal aberrations are shown in combination with the total pregnancy outcome in Table 2. Nineteen women decided to terminate their pregnancy because of the genetic result.

Table 3 shows the completed gestational weeks of every woman being observed until the end of her pregnancy and the newborn's weight.

Spontaneous abortion of the fetus having trisomy 21 occurred at the 19th gestational week, 12 days after the amniocentesis (Table 2). In addition, the fetus with 69XXX karyotype showed no heart activity at the 18th gestational week, with the amniocentesis done in 16.3 gestation weeks (Table 2). Both events, being time related to the amniocentesis and thus postprocedural, were not seen as procedure-related fetal loss because of the genetic aberrations and more than 7 days has passed between the two events.

Table 1 Color of the amniotic fluid.

Color of the amniotic fluid	Punctures	Percent
Yellow, clear	298	96.8
Yellow	1	0.3
Yellow, muddy	3	1.0
Brownish	4	1.3
Brownish, bloody	1	0.3
Bloody	1	0.3
Total	308	100.00

Three fetuses died intrauterine (Table 2): one with the karyotype 46XY and hydrops fetalis; one with 46XX who died in 37+3 weeks of gestation, with placental insufficiency and anomaly of umbilical cord; one with the trisomy 18 died after 40.1 gestational weeks.

Concerning the gestational age at delivery and the birth weight of the live-born children (shown in Table 3), 17 children were born before 37.0 completed weeks of gestation and 5 had a birth weight <2000 g. One of the mentioned low-weight children was born at 27.6 weeks of gestation and weighing 510 g. Amniocentesis was performed 1 week before birth because of extreme fetal growth restriction. The karyotype was 46XX. The patient was admitted to the hospital, and a primary cesarean delivery was indicated because of the pathological Doppler in the umbilical artery and the intrauterine growth restriction 7 days after the amniocentesis. Two other children were twins born at 30.4 weeks of gestation and weighing 1200 and 1400 g. Both left the hospital in 3 weeks in satisfactory condition. In addition, cesarean delivery of one child weighing 1850 g, born at 34+3 weeks, was done because of fetal malformations. The girl had gastroschisis and increasing polyhydramnios. The mother of the fifth child who was born at 35 weeks weighing 1550 g delivered in another clinic and, thus, their data were not available for our study.

Discussion

Our prospective study using of 29-G pencil-point needle for 316 amniocenteses clearly demonstrates that this technique as a safe alternative to amniocentesis with 22-G needle. The

Table 2 Karyotypes and their gestational outcome.

Karyotype	Live-born child	Termination of gestation	Spontaneous abortion	Intrauterine fetal death	Neonatal death	Still pregnant	Total
46XX or 46XY	231			2	2	52	292
Trisomy 21	1	10	1				12
Trisomy 18		3		1			4
Trisomy 13		3					3
Trisomy 10		1					1
Triploidy				1			1
Translocation						1	1
Polymorphism		1					1
Mar(4) syndrome		1					1
Total	232	19	1	4	2	53	n=316

Table 3 Gestational age and fetal birth weight at delivery of live-born children.

Gestational age	Deliveries	Percent	Fetal birth weight	Fetuses	Percent
Median gestational age, 39.2 weeks (interquartile range, 38.2–40.1)			Mean weight, 3327.45 g		
<30.0	1	0.43	<1000 g	1	0.44
30.0–34.6	8	3.46	1000–1499 g	2	0.87
35.0–36.6	8	3.46	1500–1999 g	2	0.87
37.0–38.6	77	33.33	2000–2499 g	11	4.80
39.0–40.6	117	50.66	2500–2999 g	36	15.72
41.0–42.6	20	8.66	3000–3499 g	79	34.50
			3500–3999 g	74	32.32
			4000–4499 g	18	7.86
			>4500 g	6	2.62
Total	231	100.00	Total	229	100.00

tip of 29-G needle not only perforates but also displaced two layers of the chorioamniotic membrane and causes fewer traumas to the fetal membranes and the uterine wall, which may reduce the probability of a hemorrhage, as shown by the results of an earlier study [15]. It was shown *in vitro* that the hole in the fetal membranes, after being punctured with the 29-G needle, is 36 times smaller than the hole produced using a 22-G needle. Amniotic fluid loss is as much as 61 times less intensive [15].

The summarized rate of complications of amniocenteses (miscarriage, amniotic fluid loss, bleeding, pyrexia, etc.) averages between 1% and 2% [1, 6, 11, 14, 16, 17]. According to these proportions and the specificity of patients in our hospital, most of whom had elevated obstetrical risk, 3–6 complications could be expected in a study of 316 amniocenteses. Nevertheless, we did not encounter any of those complications. In one case, we observed a bloody color in the amniotic fluid, but there was no bleeding after the procedure.

Odibo et al. [10] published in 2008 their experience with higher risk in cases of fetuses with structural abnormalities. We acknowledge their findings because, in our series, all seven fetuses/children with poor outcome also had a pathological karyotype or malformations.

These seven cases have to be compared with the natural second trimester fetal loss rate. Odibo et al. [10], in the same study in which they examined the total fetal loss rate after amniocentesis (0.4%; 0.97%, <24 weeks), compared the rate in the group without this procedure (0.26%; 0.84%, <24 weeks).

Certainly, the 29-G needle has its limitations. Being very thin, the short guide needle has to be deep enough into the myometrium. First, if the guide needle is not deep enough, there is an elevated risk for the 29-G needle of not being able to penetrate the membranes and thus bending. Thus, insertion to at least two-thirds of the myometrium is essential. Second, while puncturing obese patients, the short guide needle can glide out, which means that it has to be fixed during the procedure.

The small number of patients is the major limitation of this study. Despite our limited experience, we postulate this technique as a safe alternative to the previous prenatal invasive procedure. To confirm our results, a larger sample of women is needed, and a randomized, multicenter study is planned.

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