Application value of disposable anesthesia needle in amniocentesis during pregnancy

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Abstract: To compare the short-term outcomes of two different types of amniocentesis neddle under the guidance of B-ultrasound. An analysis of 72 cases of ultrasound-guided amniocentesis performed in the second trimester using disposable anesthesia-needles and conventional 22G-puncture-needles.70 amniocenteses in total were observed. No cases was considered as surgey-related fetal loss. There was no significant difference in procedure time, sampling time and puncture time. Amniocentesis using a disposable anesthesia needle seems to be a safe method, which deserves further research and promotion.

1. Introduction

With the rapid development of society and economy and the improvement of people's living standards, the whole world is very concerned about the improvement of the comprehensive quality of the population, and people's awareness of eugenics and education has been continuously improved. Most pregnant women are more concerned about the health of the fetus. Amniocentesis is one of the most important common invasive procedure aimed at obtaining a sample of amniotic fluid to assess congenital abnormalities. Thousands of amniocentesis procedures have been performed to assess congenital abnormalities since its first use in 1966[1]. At present, the amniocentesis technique is used in the second trimester of pregnancy to analyze the fetal chromosome or the urinary tract and digestive tract cells to analyze whether the number or structure of fetal chromosomes is abnormal. Currently recognized as one of the most commonly used prenatal diagnostic methods with minimal trauma to mothers and children, and is also an important detection method for eugenics [2,3,4,5]. This will help mothers and families, especially babies, in preparing for delivery and future outcomes. It is well known that its main risks include maternal or fetal trauma, infection, miscarriage or premature birth [6]. The most important risk of amniocentesis is the surgey-related miscarriage (0.11–1.00%) [7]. Other risks associated with surgery are unclear, but fetal damage has been described. In addition, the incidence of fetal skin scars after amniocentesis is estimated to be 1%–3% of women who have undergone amniocentesis in mid-pregnancy, but the rate is may be higher because infants are rarely thoroughly checked for pinhole scarring at birth and the marks are often not abvious [8].There are many individual case that report specific injuries, such as thoracic puncture, vascular damage with arterio-venus fistula formation and some severe brain injuries[9,10,11].There are few large studies to determine the incidence of fetal injury. No such difference was seen by comparing 20G and 22G needles using a sharp, bevelled tip [12]. This article compares the effects of different types of amniocentesis (disposable anesthesia needles and conventional 22G-puncture-needles) on mothers and children under ultrasound guidance, further reducing the complications of amniocentesis, and minimizing damage to pregnant women and fetuses.

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2. Material and Methods

2.1 Research object

A total of 72 pregnant women who had undergone prenatal genetic or high-risk outpatient consultation and were willing to undergo invasive prenatal diagnosis were selected from our hospital in 2018.12–2019.06. Multiple pregnancy and fetal abnormalities were excluded. All laboratory indexes of pregnant women such as routine vaginal secretions, antibodies against HIV/AIDS, hepatitis C and syphilis, hepatitis B surface antigen, identification of ABO blood group and RhD blood group, blood cell analysis results and blood coagulation test results within 3 days before operation were comprehensively tested before operation. Surgical taboos:(1) WBC≥15*109/L or N≥85%, (2) preoperative body temperature≥37.5℃ (repeated 3 times), (3) inflammatory active stages such as upper sensation, pharyngitis, severe vaginitis, hepatitis B (elevated transaminase), syphilis, etc., (4) oligohydramnios were found by B-ultrasound before operation.

2.2 Observation index

(1) General conditions such as age, times of pregnancy, (2) Operative conditions: Gestational age at amniocentesis, procedure time, sampling time, puncture time, postoperative bleeding of needle tract, probability of lower abdominal pain in pregnant women, (3) Investigation of postoperative VAS pain score of pregnant women, postoperative fatigue questionnaire of operators and pregnancy outcome.

2.3 Operation method

Every participant received an ultrasound examination through the GE Logiq E8 US system (GE Medical Systems) to confirm the gestational age and placenta location. The women were informed about any possible risks of the procedure and signed an informed consent form. All amniocentesis was performed by an operator. The skin was disinfected and sterile ultrasound gel was applied. Avoided the placenta as much as possible during operation, observed fetal movement and fetal heart condition after operation, whether there was bleeding in the needleway, and whether complications occured after surgery. Blood pressure and pulse were measured after the operation. Pregnant women were discharged from the hospital after 20–30 minutes of rest. The procedure was performed using a single-use anesthesia needle (AN-N,0.7x90mm; Henan Camel Medical Equipment Group Co., Ltd.) (Fig.1) or 22Gx150mm (YZB/JAP2749-2014 puncture needle). Instructed pregnant women to fill in the VAS pain score survey after puncture. The degree of pain was expressed by a total of 11 numbers from 0 to 10. Patients chose one of these 11 numbers based on their own pain level to represent the pain level. The operator filled out a surgical fatigue questionnaire after puncture. The scoring standard was 1–5 points. One point represented no feeling of fatigue, and five points meant very tired. The surgical fatigue questionnaire was prepared by our hospital. Ultrasound examination was performed immediately after the operation and 24–48h after amniocentesis to check fetal cardiac activity and detect any other complication. Complications occurred within 7 days after surgery.

3. Statistical

Statistical analyses were processed with the Statistical Package for the Social Sciences (SPSS), version 20.00(SPSS Inc., Chicago, IL, USA). In total,72 women were studied:36 in group A and 36 in group B. Valid data existed for 70 women:35 (group A) and 35 (group B). P value of <0.05 was considered significant.

4. Results

All surgeries were performed with a single injection, and the results are shown in Table 1.There was no statistically significant difference between an amniocentesis under ultrasound guidance using an amniocentesis using a disposable anesthesia needle rand a 22G puncture needle in mean maternal age(30.3±3.3 vs 30.5±3.5 years, respectively) or mean gestational age at the time of

amniocentesis(23.3±2.5 vs 23.8±2.3 weeks, respectively).The procedure time was longer than using 22G needle(14.23±0.55 min)compared with disposable anesthesia needle(14.1±0.6 min),although the difference was not statistically significant. Amniotic fluid aspiration volume is 13-22ml (median, 16ml). The average time to draw amniotic fluid was 3.08 minutes and 3.13 minutes respectively. There was no significant difference in puncture time (from the time of inserting needle to the time of pulling out needle), which was 3.75±0.2min and 3.67±0.2min respectively. Neither amniocentesis resulted in miscarriage during pregnancy. There was no significant difference between the two groups in the VAS score and the operator's fatigue score scale after amniocentesis (Tab.1).

5. Discussion

Since its introduction in the early 1960s, amniocentesis has become a routine procedure in invasive prenatal diagnosis [13]. Amniocentesis was often used to obtain prenatal diagnosis. Fetal genetic disease can be identified in mothers with risk factors. Therefore, pregnant women need to improve the awareness of check-ups and properly treat the amniotic fluid puncture. During the check-up, they can do the amniotic fluid extraction and laboratory analysis with the assistance of medical staff. Patient comfort and safety are important issues in amniocentesis. Although it is believed that using smaller needles can reduce trauma and complications, previous studies have not supported the theoretical statement that needles of different sizes provide no additional advantage[14,15,16].

Previous publications have included comparisons of various needle sizes, needles with improved ultrasound visibility characteristics, and other complications [14,16]. However, the feelings of surgical operators and the VAS score have not been investigated. In this study, we incorporated the above data into the design and expanded the previous data.

Previous investigations have confirmed that small needles have been certain difficulties during the operation, and that amniotic fluid aspiration takes longer due to blockage and the need for a second administration [17]. In our study, the procedure time was longer than using 22G needle compared with disposable anesthesia needle, although this difference was not statistically significant. Amniotic fluid aspiration volume is 13–22ml (median, 16ml). The median time for retrieve the amniotic fluid was not significantly longer, after all, the inside diameters of the two kinds of needles were similar. There was no significant difference in puncture time (from the time of inserting needle to the time of pulling out needle), but the disposable anesthesia needle was soft, even if it was left on the mother for a short time during the puncture, the fetus will not be affected much, and amniotic fluid can be drawn repeatedly to avoid damage caused by repeated puncture.

One of the most serious complications of amniocentesis is fetal miscarriage. According to some literature reviews, the increased risk of fetal loss following amniocentesis procedure is due to multiple attempts, blood stained amniotic fluid and the presence of fetal abnormalities [18]. No cases was considered as surgey-related fetal loss in this study. We find that there were no significant differences in the postoperative complications during amniocentesis.

While there is an increased risk of fetal puncture with less experienced obstetricians, many injuries are unpredictable due to the sudden movement of the fetus [19]. Few reports of complications after amniocentesis have been published since the advent of real-time ultrasound. Previous case reports illustrated that cutaneous scar lesions after amniocentesis. The damage to the children was limited to its aesthetic consequences[20,21].There are also reports of serious complications, such as brain damage, although rare, The consequences of fetal brain injury are severe, all cases showed evidence of disruption of brain development compatible with mid-term injury[11].From the perspective of the fetus, although normal movement is unpredictable during the diagnosis of amniocentesis, we founded that the disposable anesthesia needle can be pulled out because the needle was soft and hose remains in the body, which did not affect the fetal movement in the mother's body, which was safer for the fetus. In addition, the author believes that for pregnant women with less amniotic fluid, we can inject normal saline through a disposable anesthesia needle to supplement amniotic fluid to better meet clinical needs, but further research is needed.

Proper indication, informed consent, and experienced operator can reduce the rate of fetal loss in amniocentesis [22]. The amniocentesis is an invasive operation with high cost but very important examination items, it will increase the psychological and economic burden of pregnant women and their families. In the process of puncture, the pain of pregnant women will also increase the difficulty of operation and affect the quality of operation. There were no significant differences in the VAS score and operator fatigue during amniocentesis. Single amniotic fluid entry and reduced surgey time also reduce maternal anxiety and operator fatigue.

6. Conclusion

Amniocentesis is one of the most important prenatal diagnostic procedures available to assess congenital abnormalities. Our data shows that there are similar outcomes using two different sizes of neddles during amniocentesis procedures. Therefore the disposable anesthesia needle is safer for fetus and may also be suitable for performing amniocenteses, which deserves further research and promotion.

Table.1. Data regarding maternal age, gravidity, gestational age at amniocentesis, procedure's technical details, and pregnacny outcome in the groups of women who had amniocentesis with disposable anesthesia needle (group A) and 22G needle (group B).

	Grop A ： disposable anesthesia needle	***Group B ： 22G***	***P***
Number of women	35	35	
Demographics			
Maternal age	30.3±3.3	30.5±3.5	NS
Gravidity	1.91±0.81	1.89±0.72	NS
Details of amniocentesis			
Gestational age at amniocentesis	23.34±2.5	23.8±2.3	NS
Procedure time(min)	14.1±0.6	14.23±0.55	NS
Sampling time(min)	3.08±0.2	3.13±0.17	NS
Puncture time(min)	3.75±0.2	3.67±0.2	NS
>1 needle	-	-	-
Bleeding(5min)	1(2.86%)	1(2.86%)	NS
Leakage of amniotic fluid	-	-	-
Latrogenic pregnancy loss	-	-	-
VAS score	4.46±1.1	4.5±1.1	NS
Operator's fatigue score	2.17±0.78	2.14±0.73	NS

[a] Values are presented as means ± standard deviation or as numbers with percentages in brackets,
[b] NS： not statistically significant

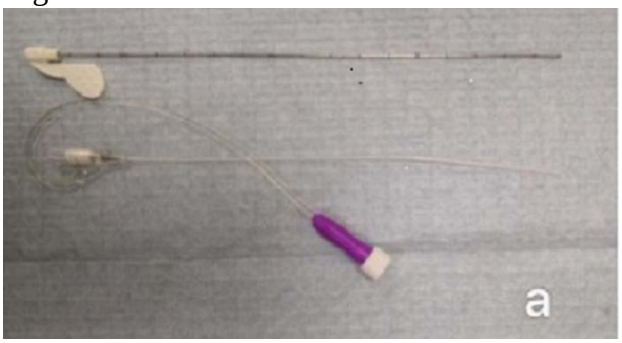

Figure 1. A disposable anesthesia needle

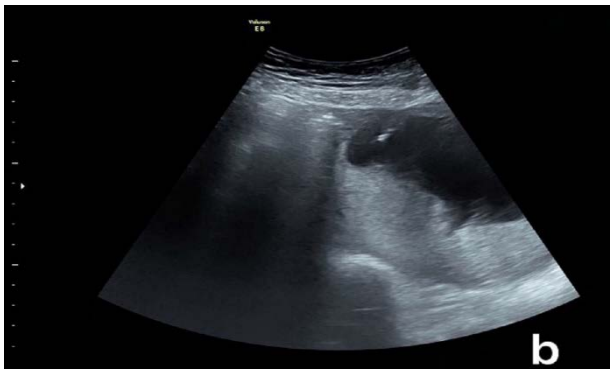

Figure 2. 22-G needle in ultrasonography

Figure 3. Disposable anesthesia needle in ultrasonography

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