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Asepsis Techniques Prior to Amniocentesis; Which Technique is Better?

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What is known on this subject?

Amniocentesis is the most common invasive technique used for prenatal diagnosis. Cutaneous asepsis before the procedure id a critical step for a safe procedure. There is no consensus or a standard for the asespsis technique before amniocentesis. We still do not know exactly which is better or may reduce the complications of the procedure.

What this study adds?

In this study, we have compared the results of the cases that the asepsis before amniocentesis was made by different techniques and we did not find a significant difference between the techniques. We conclude that the asespsis technique choice may depend on the basal risk of the pregnant women.

ABSTRACT

Objective: The aim of this study was to analyze the indications of second-the trimester amniocentesis in a tertiary center and evaluate the difference between aseptic techniques before amniocentesis.

Material and Methods: The study sample was drawn from the patients who had amniocentesis between 16th and 22th weeks of pregnancy at Trakya University high-risk pregnancy unit between 2015 and 2018. The patients were divided into two groups according to the antiseptic solutions, which used before the operation. Group I comprised of patients in whom 10% povidine- iodine solution was used for aseptic skin preparation. Group II consisted of patients in whom 10% povidine- iodine solution with 70% isopropyl alcohol solution was used.

Results: One hundred fifty eight patients were in group I and took 10% povidine- iodine solution was used for aseptic skin preparation before the procedure and 119 (42.9%) patients were in group II and 10% povidine-iodine +2% chlorhexidine gluconate were used for skin preparation. There were no fetal loss in either group. Two patients (0.7%) in group II was admitted to the hospital in the first week after amniocentesis with increased vaginal discharge and slight abdominal pain.

Conclusion: Although the lack of evidence for the superiority of any asepsis technique, a combination of aseptic solutions may be an option for the patients with a high risk of fetal loss.

Keywords: Amniocentesis, povidone iodine, chlorhexidine, fetal loss, amniotic leakage, vaginal discharge

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Introduction

Amniocentesis was first introduced in the 1950s for sex determination, and was applied to clinical practice in 1966 to obtain fetal cells for karyotyping (1). During the last 30 years, clinical indications of amniocentesis were increased by new screening tests. Advanced maternal age and a positive screening test for aneuoploidies are the most common indications of amniocentesis.

The safety of the procedure has been assessed by several trials (2,3,4,5,6,7). Reports of fetal loss due to amniocentesis differ greatly among authors, varying from 0.13 to 2.2%. New studies concluded that the procedure related fetal loss rate is are lower than that currently quoted for women (8).

The technique of amniocentesis and the experience of the operator are also important tools for the success of the procedure. In the transplacental route, the fetal loss rate of the procedure has been reported as 1.4% in a review of nine reports (9).

As a part of the amniocentesis technique, before the procedure, the operator cleans the abdomen with an antiseptic solution. Many kinds of antiseptic solutions have been used for this purpose and there is no clear evidence which antiseptic solution has better results.

In this study we have analyzed the indications of the second the trimester amniocentesis in the tertiary center and evaluate the difference between aseptic techniques and to find the best asepsis technique before the amniocentesis, if any.

Material and Methods

The study samples were drawn from the patients who had amniocentesis between 2015 and 2018 at Trakya University, Faculty of Medicine, Maternal-Fetal Unit. Pregnant was between 16 and 22 weeks of gestation. Ethical approval was undertaken from Trakya University, Ethic Committee (decision no: 04/26, date: 21.05.2018). Patiens consent was undertaken for the study. All procedures were performed by experienced operators with 22 gauge needle, under ultrasound guidance using commercially available real time machines (Voluson 730 Expert/Voluson E6, General Electric, Tiefenbach, Austria) with a 4-to-8-mHz probe (RAB 6D). The mean volume of the obtained amniotic fluid was 20 mL. Different solutions were used for skin preparation according to operator's choice. All the steps were recorded in the patient's file. Every patient was warned about the signs of fetal loss and ıt was advised to come to the hospital in cases of any bleeding, abnormal vaginal discharge, pain, or cramping. All patients were called by phone for controlling after two weeks.

Demographic data of the patients, indications for amniocentesis, and the route of the operation (non-placental-transplacental) were recorded. Patients with multiple pregnancy, known uterine anomalies, fibroids and cervical incompetence, history of three or more abortions in the first trimester and the second trimester miscarriages were excluded from the study. Women with serious maternal illness, morbid obesity and bleeding that occurred in last two weeks were also excluded from the study.

The patients were divided into two groups according to the antiseptic solutions that used before the operation.

Group I consisted of patients in whom 10% povidine-iodine solution was used for aseptic skin preparation.

Group II consisted of patients with 10% povidine- iodine solution and 2% chlorhexidine with 70% isopropyl alcohol solution were used.

The necessity of hospital visit before the control exam at the second week of the procedure was recorded. Pain, vaginal discharge and other complaints were questioned at the control exam and the fetus was controlled for fetal heart activity by sonography.

Fetal loss, amniotic leakage and the other complaints of the patiens were analysed in both groups.

Statistical Analysis

Statistical analyses were performed using the Number Cruncher Statistical System (NCSS 2007) (Kaysville, Utah, USA). Data were analyzed using descriptive statistical procedures (mean, median, frequency, standard deviation, minimum, and maximum). Student's t-test was done to compare normally distributed variables, while Mann-Whitney U test was used to compare variables, which were not normally distributed. Fisher's Exact test and Yates' continuity correction test were preferred to compare the data. $p<0.05$ was considered statistically

Results

During the study period 277 patients were fulfilled the inclusion criteria. mean maternal age was 32.3 (17-46) of the patients.

The indications for amniocentesis were triple test in 77 (27.7%) patients, triple test and the second trimester sonographic marker in 25 (9%) patients, triple test and advanced maternal age in 20 (7.2%) patients, sonographic findings and major anomalies in 86 (31%) patients, a double

test in 37 (13.3%) patients, non-invasive prenatal test in 5 (1.8%) patients, maternal request in 5 (1.8%) patients and advanced maternal age and sonographic marker in (113.9%) patients.

The remaining (3.9%) patients underwent amniocentesis because of genetic indications as familial genetic disorders and previously born of a child with a genetic anomaly.

The route, which used during the procedure was transplacental route in 75 (27.7%) patients and placental route in 202 (72.9%) patients.

Of 158 patients in group I, 10% povidine- iodine solution was used for aseptic skin preparation before the procedure and 119 (42.9%) patients were in group II and 10% povidine-iodine +2% chlorhexidine gluconate with 70% isopropyl alcohol solution were used for skin preparation.

There were no fetal loss in both groups. Two patients (0.7%) in group II were admitted to the hospital in the first week after amniocentesis with increased vaginal discharge and slight abdominal pain. In the vaginal examination, there were no signs of amniotic leakage, but amnisure tests were positive for amnion fluid. There was no amniotic leakage in the following observation at 24 h and was thought to have stopped spontaneously.

There were no statistically significant differences between the complaints and hospital visits of the groups during the follow-up. There were also no statistically significant differences between the clinical findings of the patients on the control exam day (Table 1).

Table 1. Findings of the patients after the procedure

	Group I (n=158)	Group II (n=119)	p-value
Amniotic leakage	2	0	NS
Pain	2	2	NS
Hospital visit before control	2	1	NS
Pathologic findings at the control visit	0	0	NS

NS: Not significant

Discussion

In this retrospective controlled study, we evaluated the solutions used for abdominal skin preparation before amniocentesis. In our study population, 10% povidine-iodine solution and 10% povidine- iodine solution and 2% chlorhexidine were used for skin preparation according to operator's choice.

There was no clear evidence for the superiority of one solution to oher and combination of solutions before amniocentesis. We also still do not know exactly that complications of amniocentesis may be affected by the asepsis technique.

The literature on the efficacy of these agents is conflicting. Some studies found alcohol-based chlorhexidine (0.5 2%) to be superior to povidone iodine 10% for cutaneous antisepsis (10,11).

Several studies report equal effectivity for these agents (12,13,14).

No difference has been found between 2% chlorhexidine and 10% povidine-iodine for skin disinfection with regard to costs, efficacy and side effects in a prospective randomized study (14).

The most important challenge of the amniocentesis is the risk of loss of a healthy fetus during a diagnostic test. So the factors, which increase the background risk of fetal loss after amniocentesis are critical. It has been reported thar advanced maternal age, bleeding in the current pregnancy and history of the three or more first trimester abortions and/or the second trimester miscarriages seem to be significant predisposing factors for fetal loss (15).

We have excluded the patients with a history of the three or more first trimester abortions and/or the second trimester miscarriages from our study. Bleeding during the current pregnancy was also an exclusion criterion.

Some studies on this topic have been reported but it is still unknown whether the choice of antiseptic solution impacts the fetal loss risk of amniocentesis.

The reduction of fetal loss has been reported with the change of aseptic procedure from 2% clorhexidine to more potent chlorapep (2% chlorhexidine and 70% isopropyl alcohol) from a retrospective cohort (16).

The bacterial flora of the abdominal skin was assessed by abdominal swabs and has been shown that 2%. Chlorhexidine with 70% isopropyl alcohol is superior to povidine- iodine for cleansing the maternal abdomen before amniocentesis (17).

In that study, no statistically significant difference was detected between baseline colony counts between the left and right side of each patient's abdomen before cleansing. Post cleansing colony counts were revealed that chlorhexidine is a more effective abdominal cleanser.

We do not know whether these findings affect the fetal and maternal side effects of amniocentesis.

In our study, we compared the clinical findings and adverse events in both groups for 15 days after amniocentesis that could be related to the procedure itself.

We found no significant differences in the clinical findings between the groups. Although it was found to be unsignificant, two cases of amniotic leakage occurred in group I. The complaints of these two patients were "increased vaginal discharge". We could not unable to see the leakage in the vaginal exam, but the amnisure tests of the patients were positive for amniotic leakage. The vaginal discharge stopped and the pregnancy continued in both cases. The patients were observed for 24 h and called for a control examination one week later The sonographic findings of amniotic volume, fetal cardiac activity and the other sonographic measurements of the fetuses were completely normal at the control examination. Maternal fever, infectious markers in the blood test and clinical findings of the pregnant were also evaluated and found as completely in normal ranges.

Despite the high ratio of good prognosis, transient amniotic leakage is an important event after amniocentesis because of the possible association with fetal loss and chorioamnionitis.

In the review of the literature, it was found that amniotic leakage is an uncommon complication of amniocentesis. Conservative management with bed rest seems to yield good results. If the leakage does not persist, spontaneous resolution usually occurs (18).

Transient amniotic leakage has been reported as 2% after fetoscopic laser coagulation for twin transfusion syndrome (19).

Prolonged residual effect and the bactericidal effect of chlorhexidine against *Staphylococcus* make it a preferable agent for cutaneous antisepsis; but there is no clear evidence for its superiority of for antisepsis before amniocentesis.

Study Limitations

In this study, we have retrospectively evaluated the cases of amniocentesis that met our inclusion criteria. In our study time interval 277 patients met the inclusion criteria of the study. One hundred fifty nine patients were in group I and 119 patients were in group II. The antiseptic solutions were the choice of the operator. We have found the details of the operations and the clinical findings on the control exam day from the patient's files. Thus, the study was meticulously selected but the sample size was small to evaluate the effects of antiseptic solutions because of the rarity of the complications.

Conclusion

To determine the superiority of the solutions to each other and combination of the solutions before the amniocentesis and to ro evaluate the relation of the amniotic leakage cases with antiseptic solutions, larger prospective studies are needed.

Nevertheless, it is logical to use a combination of both the antiseptic solutions especially in the patients who have a high background risk of fetal loss and infection.

Ethics

Ethics Committee Approval: Ethical approval was undertaken from Trakya University Ethics Committee (decision no: 04/26, date: 21.05.2018).

Informed Consent: Patiens consent was undertaken for the study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: I.U.Ç., C.S., F.V., C.İ., H.S., S.E., Concept: I.U.Ç., C.S., F.V., H.S., S.E., Design: I.U.Ç., C.S., F.V., C.İ., S.E., Data Collection or Processing: I.U.Ç., C.S., S.E., H.S., Analysis or Interpretation: I.U.Ç., F.V., C.S., C.İ., Literature Search: I.U.Ç., F.V., C.S., S.E., H.S., Writing: I.U.Ç., F.V., H.S., S.E.

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