

A Simple and Practical Amniocentesis Model and the Procedure Success Rate After Training

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ABSTRACT

Objective: To compare success rate of amniocentesis between model trained and non-model trained groups.

Methods: Siriraj amniocentesis simulator was practiced by 5 inexperienced obstetric residents. Forty aspirations of red solution from the targeted balloons using spinal needle number 20-G under the ultrasound guidance were performed. Thereafter, each trainee was allowed to perform the real amniocentesis under an expert supervision within a 5-minute period. Amniocentesis success rate of previous 5 non-model trained residents was retrospectively reviewed and considered as the control group.

Results: A comparison between each group was done to evaluate the success rate. There were 31 and 29 of amniocenteses performed by model trained and non-model trained groups, respectively. In comparison, the former had a non-significantly higher success rate (96.8% vs 82.2%; $p > 0.05$) with a significantly shorter operating time (34.27 ± 21.7 vs 73.38 ± 68.5 seconds; $p < 0.05$) than the latter. No obstetric adverse outcome was observed in both groups.

Conclusion: The amniocentesis-training program with model is beneficial for the beginners to develop their skill prior to the real practice, especially shorter operating time. There was a trend of higher success rate in the model-training group.

Keywords: Amniocentesis; success rate; training model; operative time (Siriraj Med J 2018;70: 6-11)

INTRODUCTION

Amniocentesis is a common invasive procedure performed during pregnancy for a variety of diagnostic and therapeutic indications. Amniocentesis for prenatal diagnosis is usually performed between the 15th and 20th week of gestation. Major complication associated with amniocentesis are rupture of membranes occurring 0.1-1.7%.¹⁻³ Chorioamnionitis was present less than 1% whereas post procedural fetal loss was reported to be 0.6-1%.⁴⁻⁷ Recently, post procedural abortion rate has been reported as low as 0.11% in one meta-analysis.⁸ In the past, obstetric residents performed amniocentesis procedure using freehand technique under close supervision of the expert without prior model training. To achieve high success rate, the operators were required to skillfully and accurately insert a needle to the target and gently

aspirate the amniotic fluid with ultrasound guidance. Therefore, we have innovated "Siriraj amniocentesis training model" to facilitate the beginners to practice and earn their operative proficiency without any harm to the patients. Thereafter, a one-week training program with 40-aspiration achievements was obligated prior to the actual amniocentesis. The main objective of this study was to compare the success rate and duration of amniocentesis performed between the model-trained group and previous non-model trained group.

MATERIALS AND METHODS

The research was conducted as a cross-sectional study at Maternal-Fetal Medicine Unit, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, Mahidol University with an approval

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of the institutional ethics committee (Si 260/2007). The medical records of pregnant women who underwent amniocentesis performed by ten 2nd year obstetrics and gynaecology residents between June 1, 2006 and May 30, 2007 were extensively reviewed. All participants (he or she) with average age of 25 years old had never before performed any invasive prenatal diagnosis. They were classified into non-model trained and model trained groups. Before the model invention, all apprentices in the past had to attend and assist the expert to perform amniocentesis for at least five procedures before they were subjectively evaluated and allowed to do the real procedure under supervision. The data of amniocentesis performed by five last non-model trained residents were retrospectively reviewed as the control group.

In the latter group, a 1-hour teaching session of amniocentesis simulator was prepared for each trainee, which consisted of five residents for 1 week. At the end of the session, their performances were systematically evaluated by one fetal medicine specialist (PC) using the assessment criteria of probe holding technique, needle control skill, target achievement, and operative time. The amniocentesis success rate performed by five model-trained residents were analyzed and compared to the first group.

All pregnant women had met the inclusion criteria of 1) singleton pregnancy 2) gestational age of 16-20 weeks 3) fulfilled the indication for amniocentesis such as advanced maternal age, familial history of abnormal chromosome, abnormal ultrasonographic finding of fetus and abnormal serum screening test results. Multifetal pregnancies or therapeutic amnioreduction were excluded from the study.

The Training Model and Practicing Program

Siriraj amniocentesis training model is designed by using the commercial household equipment consisting of a medium-sized (30 x 22 x 12 cm.) kitchen plastic food storage container with a waterproof lid. The center of the lid is removed in rectangular shape to make a plastic frame attached with a rubber sheet (17 x 25 cm.). This container is used to simulate intrauterine environment as the lid works as an anterior abdominal wall of a pregnant woman. Another rubber sheet is placed on the bottom of the container to prevent sonographic reverberation effect from the ultrasound probe. Then, the targets are prepared by using 5 or more elastic rubber balloons in different sizes filled with the red solution (few drops of Utaitip Thai herbal tint (Osotspa Company, Thailand) dissolved in 500 ml water). This red tint is made from numerous herbs namely Fang Yuan, Safflower, Saffron,

Cinnamon, Jasmine and Lotus pollen. All balloons are finally tied to the rubber floor firmly to act as a target of needle aspiration. To make the sonographic visualization more realistic, a 20-week size of fetus dummy is placed alongside the balloons. It will help the beginner to develop needle control skill and make no harm to the fetus inside the uterine cavity. Finally, 8,000 ml of water is fully filled into the plastic container and the lid is perfectly sealed as shown in Fig. 1 and 2.

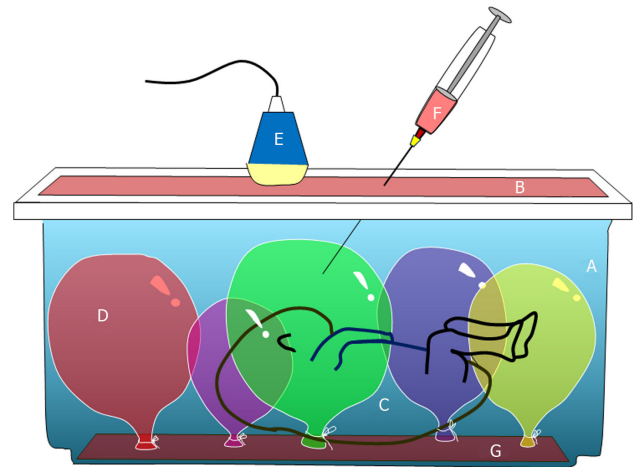


Fig 1. Siriraj amniocentesis training model diagram. A) Transparent plastic box (30 x 22 x 12 cm.). B) Cover lid with a rubber sheet in the middle. C) Fetal dummy (20-week size). D) Elastic balloons filled with red solution tied to the rubber floor. E) Transabdominal ultrasound probe. F) A 20-G spinal needle with a 10-ml. disposable syringe. G) Rubber sheet at the bottom.



Fig 2. Siriraj amniocentesis training model assembly. A) Top view. B) Close the lid. C) Side view. D) Top view of the model sealed with the lid.

During the one-week of practice, each trainee had to puncture the balloons by using a 20-gauge spinal needle under ultrasound guidance as shown in Fig 3. (Model Logiq 3, General Electric Company, Waukesha, U.S.A., and a convex transabdominal probe of 3-7 MHz). To accomplish this, one had to advance the needle towards the target correctly and aspirate the red solution from

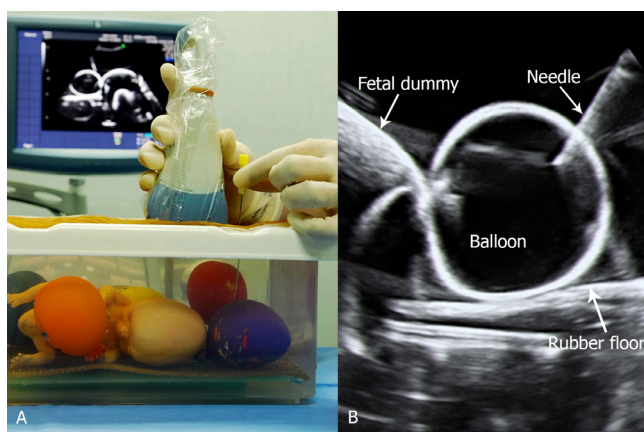


Fig 3. Amniocentesis training program. A) In training practice. B) Ultrasound findings.

the balloons for 40 successive times. At the end of the program, the trainees should be able to orientate transabdominal ultrasonographic probe appropriately and control needle efficiently. Thereafter, they will be allowed to perform the real amniocentesis under strict supervision.

In both groups, the amniocentesis was performed by using freehand technique under the expert supervision with transabdominal ultrasound guidance. A real time ultrasonographic scanner permitted confirmation of number, viability gestational age, location of placenta and the targeted amniotic fluid pocket. The puncture site was chosen based on the accessibility and quality of visualization. The procedure was carried out in an outpatient setting with sterile technique. The amniotic fluid of 20 ml. was aspirated using a 20-gauge spinal needle. Each trainee was limited to perform the procedure within 5 minutes per attempt. The duration was measured from

the time the needle was inserted through the maternal skin until the aspiration was successful and the needle was withdrawn. Thereafter, the puncture site was observed for bleeding and the fetal heart rate was monitored for 30 seconds. The procedure was considered as failure if more than one attempt of uterine puncture occurred or the duration lasted longer than 5 minutes. In such case, the supervisor would take the responsibility to finish the procedure.

All relevant demographic data of pregnant patients as well as duration of procedures, placental site, route of procedure (transamniotic or transplacental), number of needle punctures, and related complication within 2 weeks after procedure were evaluated and compared between the two groups. Statistical analysis was performed by SPSS version 18.0 for windows (SPSS Inc., Chicago, IL, USA). Patient's demographic data were analyzed regarding mean, percentage, mean difference, standard deviation, and confidence interval. The Pearson Chi-square and Fisher's Exact test were used for the comparison between the groups. The independent sample *t*-test was used for comparing descriptive demographic data between the groups. *P*-value of less than 0.05 was considered statistically significant.

RESULTS

Sixty medical records of pregnant women who underwent amniocentesis were eligible for this study. Thirty one cases were performed by model trained group and the remaining were done without. The data showed no difference of demographic data between both groups. The maternal age ranged from 23 to 46 years with gestational age of 18 weeks (Table 1).

TABLE 1. Demographic data in both groups were presented in mean \pm standard deviation.

Characteristic data	Model-trained group (Range or %)	Non-model trained group (Range or %)
Age (years)	37.32 \pm 3.439 (26-46)	36.76 \pm 4.09 (23-43)
Body mass index (kg/m ²)	22.69 \pm 3.36 (17.78-32.47)	24.08 \pm 2.85 (18.90-29.62)
Gestational age (weeks)	18.71 \pm 1.189 (16-21)	18.48 \pm 0.95 (16-21)
Amniocentesis indications		
Advanced maternal age	28 (90.3%)	27 (91.7%)
Previous abnormal chromosome child	2 (6.5%)	2 (6.9%)
Others	1 (3.2%)	0 (0)

The most common indication for amniocentesis was advanced maternal age followed by previous abnormal chromosome child. The number of posterior placenta was slightly higher than the anterior placenta and transamniotic approach was the major route (83.3%) in both groups (Table 2).

Regarding the success rate, there was a trend towards the model trained group than that of the non-model trained group although the results were not significantly

different (96.8% vs 82.2%; $p > 0.05$, Fisher's exact test). The mean duration of procedure in model trained group was 40 seconds shorter than that of non-model trained group with statistical significance ($p < 0.05$) (Table 3). Among six failure procedures, five of them were from the non-model trained group. The most common cause of failure was from needle disorientation. Neither amniotic fluid leakage nor fetal death was observed within 2 weeks after procedure.

TABLE 2. Data of amniocentesis procedure.

Characteristic data	Model-trained group (n=31)	Non-model trained group (n=29)
Placental site		
Anterior	14 (45%)	12 (41.4%)
Posterior	16 (51.6%)	17 (58.6%)
Lateral	1 (3.2%)	0
Puncture approach		
Transamniotic	28 (90.3%)	22 (75.9%)
Transplacental	3 (9.7%)	7 (24.1%)

TABLE 3. Comparison of the success rate and duration of amniocentesis procedure between model trained and non-model trained groups.

Group	Cases	Failure	Success rate	P-value (<0.05)	Mean Duration (sec)	Range (sec)	P-value (<0.05)
Model trained	31	1	96.8%	0.098	34.27	15-130	0.006
Non-model trained	29	5	82.8%		73.38	17-300	

DISCUSSION

Amniocentesis is a common and useful invasive technique performed during second trimester of pregnancy for a variety of diagnostic and therapeutic indications. With the use of assisted reproductive technology in advanced age women, the high incidence of multifetal gestations has also dramatically increased. Regarding the first-trimester fetal aneuploidy screening including cell-free DNA test, its high performance has a large impact to the decreasing number of total invasive procedures especially amniocentesis.^{9,10} This procedure is sometimes challenging and may lead to adverse fetal complications. In the past, post procedural fetal loss rate in singleton pregnancy and uncomplicated twin pregnancies were reported to be 0.6-1%⁴⁻⁷ and 0.96%,¹¹ respectively. To gain

experience, the beginner required practice on many human subjects. Initially, the learning curve of each performer was obtained slowly under the stressful supervision. As a result, the procedure related complications and adverse outcome may increase. Therefore, preclinical training with simulation model is essential and encouraging for all beginners to minimize the fetal risk.¹²⁻¹⁵ As a result, post amniocentesis fetal loss rate has recently been reported as low as 0.11% in one meta-analysis.⁸ In the future, prenatal invasive test like amniocentesis will only be preserved for the authorized operators who can complete model-training course.

Obviously, the model helped the trainee to be familiar with probe orientation and needle control shortly after training. Our data showed the favorable outcome in

the model trained group with the higher success rate and the shorter procedure duration compared to the non-model trained group. Maher JE, et al reported an amniocentesis stimulator for training since 1998.¹⁶ However, to construct the model is a time consuming process in which gelatin mixture must be prepared and preserved in the refrigerator 8 to 12 hours before the training session. Recently, several amniocentesis-training models have been proposed to simulate the real procedure and facilitate the beginner to develop operative skill with impressive outcome.¹²⁻¹⁴ Some of the simulators require fresh meat including chicken breast, beef heart, pig's uterus and embryo to imitate subcutaneous fat, uterus and fetus.^{12,17} In practice, these raw materials are costly and hard to preserve and may generate undesirable odor.

Therefore, we have designed our own simple but practical amniocentesis instructional model for a one-week training course. Aforementioned, it is constructed from safe and available household materials which costs lower than 30 US dollars. The whole unit is convenient to be prepared and assembled within 20 minutes. It is also very easy to clean up and preserve the model without any decomposing materials. The only consumable part of this model is the targeted balloons which need to be replaced after training. By changing the size and the position of balloons, the angle between the needle and probe can be adjusted to improve the skill. The balloon may be replaced by disposable examination gloves or condoms if necessary.¹⁸ The red solution allows the operator to self-evaluate the success of the aspiration and it could be omitted or be replaced by any other color solution.

The disadvantage of our model is not to offer real tissue resistance sensation during puncture. However, it allows the learners to develop the most essential skill of keeping the needle track inside the ultrasound beam towards the targeted balloon. Additionally, the use of this model can make both operators and patients overcome anxiety during the clinical practice. The most common cause of amniocentesis failure in this study resulted from needle disorientation found mainly in the non-model trained group. However, no serious complication was observed in both groups.

Since then, every obstetrics and gynecologist resident in the 2nd year of training in our department has to attend one-hour teaching session with the expert. They have to complete the amniocentesis model-training course with 40 successful balloon aspirations before being allowed to perform the real amniocentesis under strict supervision. According to our annual report, there were at least 1/3 of the total amniocenteses which were performed by

2nd year residents per year. Our study of 3,307 patients from 5-year data collection revealed that total pregnancy loss within 4 weeks of amniocentesis was only 0.2% (95% confidence interval, 0.1%-0.4%) which was lower than previous reports and comparable with the recent meta-analysis review.⁸ This finding obviously represented the high-quality performance of our institute and also reflected the impact of the amniocentesis skill of the operators acquired by the model training program.

In summary, our data shows that the amniocentesis-training program with model is beneficial for the beginners to develop their skill prior to the real practice, especially shorter operating time. There is a trend of higher success rate in the model-training group.

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Disclosures of Potential Conflicts of Interests

All authors in this research have no potential conflict of interest.

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