Experience of the First 50 Cases of Cordocentesis after Training with Model

Fuanglada Tongprasert, MD*, Theera Tongsong, MD*,
Chanane Wanapirak, MD*, Supatra Sirichotiyakul, MD*,
Wirawit Piyamongkol, MD*, Pharuhas Chanprapaph, MD*

** Department of Obstetrics and Gynecology, Faculty of Medicine, Chiang Mai University, Chiang Mai*

Objective: *To describe the experience of the first 50 cases of cordocentesis after practicing with cordocentesis model.*

Material and Method: *Cordocentesis model consisted of a water-filled transparent glass box covered with a rubber latex sheet with or without piece of pork skin. A 30-cm umbilical cord filled with mercurochrome, hung inside the container, was the target for the puncture. As in real practice, the trainee had to try to aspirate the red mercurochrome from the umbilical cord using a spinal needle under ultrasonographic guidance. After practicing with the model for 300 procedures, the trainee was allowed to perform cordocentesis on pregnant women at gestational age of 18-22 weeks by herself under expert supervision with time limit of 30 minutes. The procedure not successful in 30 minutes was considered failure. Duration of procedures, placental site, puncture site, and related complications were recorded for subsequent analysis.*

Results: *After practicing with model for 300 procedures, real cordocentesis was performed by the trainee on 50 pregnant women. The success rate in obtaining fetal blood within 30 minutes was 100%. Most of them (92%) took less than 10 minutes to complete the procedure. Puncture site bleeding and fetal bradycardia were the most common immediate complications, found in 30% and 8% respectively, and spontaneously resolved within few minutes.*

Conclusion: *Without any fetal and maternal jeopardy, cordocentesis model is simple, inexpensive but highly effective for the beginner to gain their experience, skill and prepare themselves for cordocentesis with confidence. However, the reduction of fetal loss rate with the training program remains to be further tested.*

Keywords: *Cordocentesis, Training model*

J Med Assoc Thai 2005; 88(6): 728-33
Full text. e-Journal: *http://www.medassocthai.org/journal*

Cordocentesis or percutaneous umbilical blood sampling has been used for 20 years[1]. Direct access to the fetal vascular circulation allows improvement of prenatal diagnosis and therapy. Despite its advantages and high acceptance, fetal blood sampling is relatively invasive and limited for a skilled perinatologist. The procedure-related complications are dependent directly upon the skill and experience of the operator[2]. This skill is earned almost entirely by experience, which in turn, increases proportionately with the growing number of procedures performed. Therefore, it is necessary for the trainees to practice more and more to develop their skill and lower the associated complications. In many centers, there may not be a large enough number of pregnant patients requiring cordocentesis, thereby making it difficult to acquire skill and experience. Although the models for training cordocentesis are previously developed in other centers[3-5], those are still expensive and impractical for training in developing countries. Above of all, the efficacy of practicing with those models have never been well evaluated.

Considering these problems, the authors developed own cordocentesis model, CMU 2000, in order to achieve the highest success rate and lowest

Correspondence to : Tongprasert F, Department of Obstetrics and Gynecology, Faculty of Medicine, Chiang Mai University, Chiang Mai 50200, Thailand. Phone: 0-5394-5552, Fax: 0-5394-6112, E-mail: fpunyath@mail.med.cmu.ac.th

complications in the real practice, especially at the beginning of the learning curve.

The objective of the present study was to describe the experience of the first 50 cordocentesis procedures after complete practicing with training model, in term of success rate and time consumed in each procedure.

Material and Method

A 18 x 35 x 15 cm rectangle transparent glass box, sealed each corner with water resistant glue, was used to simulate the uterine environment. To prevent reverberation effect from ultrasonic signal, a rubber latex sheet was placed at the bottom of the glass box. A 30-cm umbilical cord was filled with red solution of Mercurochrome after complete blood clot evacuation. Its both ends were tied with cord tape, then hung inside the glass box which was full of water and used as the target for the puncture. It was important to adjust the level of umbilical just 5 cm below the upper surface.

Nylon net cover consisted of 2 parts of a plastic frame and nylon net attached to plastic frame. There were 12 tiny holes around the plastic edge for tying the string to fix a rubber latex sheet or pork skin. To make an artificial anterior abdominal wall, the nylon net cover was placed on the top of the glass box, then a rubber latex sheet or a piece of pork skin (skin, muscle and subcutaneous fatty layers) was fixed over the cover (Fig. 1). For the first half of practice period with model, the rubber latex sheet was used to practice because of its less sound wave absorption, which provided brighter and clearer image. During the latter half, to gain more experience, practicing with pork skin cover was used to make better sensation of the real anterior abdominal wall of pregnant woman and improve the skill.

How to practice

The necessary instruments for training were composed of a cordocentesis model described above, an ultrasound machine (Aloka Model SSD 680EX, transabdominal curvilinear transducer of 3.5 MHz, Tokyo, Japan), a 22 gauge spinal needle and a 2 ml plastic disposable syringe for aspiration. As in real practice, the operator had to search for the puncture site of the umbilical cord under transabdominal ultrasound guidance in both cross sectional and sagittal plane. Then, the trainee had to punch the needle into the rubber or pork skin cover as close as possible to the probe and try to point it towards the umbilical cord (Fig. 2). It was very important to pass the needle along the ultrasound beam by following the sparkling sign of needle's tip (Fig. 3). As soon as it reached the umbilical cord, adjusted the needle's tip and its direction of puncture through the middle of the cord caliber, and then punched the needle speedily by wrist jerking to penetrate into the umbilical vessel.

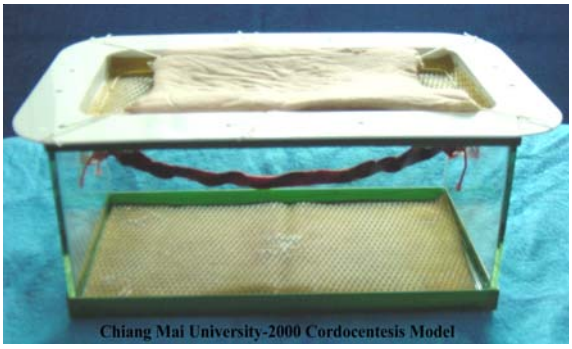

Fig. 1 Cordocentesis training model

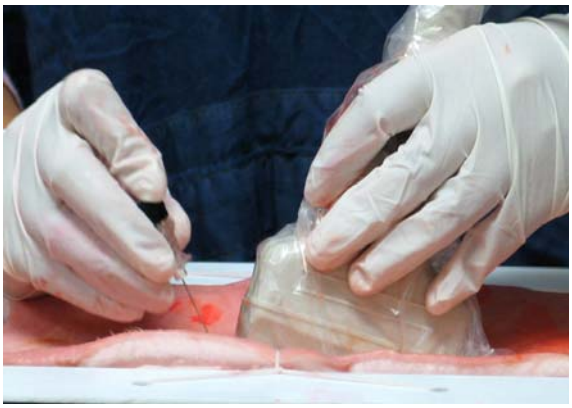

Fig. 2 Training with the model

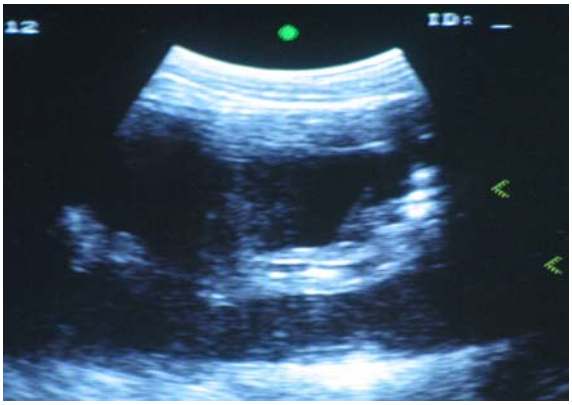

Fig. 3 Ultrasonographic picture of the umbilical cord with spinal needle on the right upper corner

Then, try to aspirate mercurochrome with disposable syringe as performing in the real cordocentesis.

Training course with the model

Cordocentesis training program had been developed for cordocentesis training within 15-day period. The trainee had to successfully aspirate Mercurochrome for 20 times per day. At the end of the training, it was expected that the trainee would have performed a total of 300 procedures on the model, and was able to orientate transabdominal ultrasonographic probe, and control needle confidently.

Real practice

After complete the training course with model, the trainee (the first author) was allowed to perform cordocentesis on pregnant women at gestational age of 18-22 weeks by herself under expert supervision with time limit of 30 minutes. The procedure not successful in 30 minutes was considered failure and the supervisor, who was always available nearby, would take over to complete the procedure. Duration of procedures, placental site, puncture site, and related complications were recorded for subsequent analysis. The pregnant women who met the criteria as follows: 1) singleton pregnancy, 2) gestational age of 18-22 weeks, and 3) proper indications for cordocentesis, were invited to join the study with fully informed and written consent. The present study was conducted with the approval of the ethic committee, Faculty of Medicine Chiang Mai University.

The cordocentesis was performed with free-hand technique under transabdominal ultrasound guidance, using the convex transduser of 3.5 MHz (model SSD 680EX, Prosound SSD 5000, Aloka, Tokyo, Japan). With aseptic technique, the procedure was carried out as an outpatient setting with the aid of real-time ultrasound scanner to confirm number, viability, gestational age, normality, location of placenta and site for puncture. A 22- or 23-gauge spinal needle was used under local anesthesia without fetal paralysis. The puncture site, either near cord insertion or free-floating loop, was chosen based on the accessibility and quality of visualization as well as an attempt to avoid placental penetration, regardless of location. One milliliter of fetal blood was aspirated into two 1-ml dispossable syringes, which was sent to the laboratory upon the indications. After the needle was removed, the puncture site was observed for bleeding, and fetal heart rate was assessed. The patients were allowed to go home after the procedure without prophylactic antibiotics or tocolysis. Rh-negative women were given an anti-D immunoglobulin prophylaxis. If needed, a simple acid elution test was used for differentiating fetal and maternal blood before fetal blood analysis. The patients continuing pregnancy were followed and taken cared as high risk pregnancy until delivery and the outcomes were recorded. The primary outcomes included the success rate and the duration of the procedures, the time from needle insertion into abdominal wall and fetal blood were obtained. The secondary outcomes included immediate complications such as fetal bradycardia and bleeding from the puncture site.

Results

The results can be summarized as shown in the Table 1. After practice with model for 300 successful procedures, real cordocentesis was performed by the trainee on 50 pregnant women. The success rate in obtaining fetal blood within 30 minutes was 100%. Most of them (92%) took less than 10 minutes to complete the procedure. Mean ($\pm$ SD) time used for the successful procedure was 3.92 $\pm$ 5.13 minutes (1-27 minutes). Multiple puncture sites were required in 2 cases (4.00%). The longest procedure was 27 minutes because the cord kept sliding away from the needle tip after vigorous fetal movement. Puncture site bleeding and fetal bradycardia were the most common immediate complications, found in 30% and 8%

Table 1. Data of the first 50 cordocentesis procedures

	Cases (%)
Placenta location	
• Anterior	20 (40%)
• Posterior	27 (54%)
• Fundus	2 (4%)
• Lateral	1 (2%)
Puncture site	
• Free loop	47 (94%)
• Cord insertion	3 (6%)
Outcome of the procedures	
• Success	50 (100%)
• Non success	-
Duration of the procedures	
• Time less than 10 minutes	45 (90%)
• Time more than 10 minutes	5 (10%)
Multiple puncture sites	
• Yes	2 (4%)
• No	48 (96%)
Complications	
• Bleeding from puncture site	15 (30%)
• Fetal bradycardia	4 (8%)

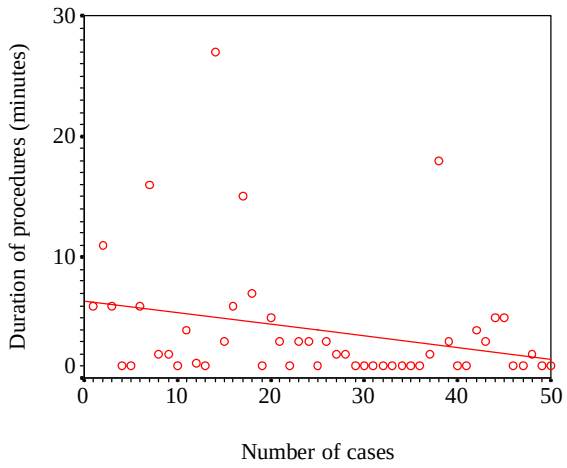

Fig. 4 Duration of the procedures after training program with the increasing number of procedures performed

respectively, and spontaneously resolved within few minutes. No fetal loss was observed in all cases, which continued pregnancies.

As shown in Fig. 4, duration of the procedures after training program was declined with the increasing number of procedures performed.

Discussion

The availability of cordocentesis has expanded the prenatal diagnosis and therapeutic options available to perinatologists. Such fetal blood sampling, however, is a difficult and potentially life-threatening procedure in inexperienced hands. The development of the skill usually requires the use of human subjects under limit investigational criteria and consent. In many centers, there may not be a large enough number of pregnant patients requiring cordocentesis, this makes the procedure much more difficult to acquire skill and experience.

To develop skills for cordocentesis, the authors constructed a model allowing the operator to become familiar with the orientation of the umbilical cord and sampling needle. The authors' experience with the model has been very favorable. The operator can confidently approach with the real situation, and successfully perform all of 50 procedures. Beside that, most of the procedures take time less than 10 minutes and cause no more immediately complications. After fetal intravascular accessibility is mastered, it is possible to proceed to more invasive difficult procedures of performing intrauterine blood transfusions or other intrauterine fetal therapies.

The authors believe that preclinical training is essential before starting real ultrasound-guided invasive procedures in fetal medicine, and that the cordocentesis model can help the inexperienced operators in their first steps for development of a skill with no patient risk. Furthermore, the model consists of inexpensive simple material that can be easily prepared in any health care center. This model practice was probably helpful in adjusting the probe and umbilical cord leading to improvement of the needle control under ultrasound guide.

Notably, the time used for each procedure is about 4 minutes on average. This is comparable with the time used by most experienced or skilled operators. In the extensive experience in our hospital, it was found that in the time of training without using model, the mean duration per procedure for the first 50 cases of practice and later period of all operators were significantly different, 20.2 ± 10.6 and 8.5 ± 7.5 minutes, respectively ($p < 0.05$; Student's t test)[6]. Obviously, the skill in the first 50 cases of the trainee in the present study was comparable to the extensively experienced operators. Therefore, the present study suggested that training with model can shorten the learning curve or even immediately skip the beginning period of learning curve to the level of experienced curve. In the authors' extensive experience, at the beginning of learning curve the procedure is not only more time consuming but the complications are likely to develop in this period of learning. Although, the trainee in the present study may not represent all trainees, at least, the present study suggests the benefit of the model training and it seems to us that training cordocentesis without practice without model first may be not justified any more.

Furthermore, the immediate complications such as transient fetal bradycardia, bleeding from the puncture site or multiple punctures were similar to those in previous reports. For example, transient fetal bradycardia (less than 1 minute) is a common complication of cordocentesis, with reported rate ranging between 3-12%[7]. Bleeding from the puncture site, which is rather common, was reported to occur in 20-53%[7].

Based on this beginner experience, it seems that the puncture site does not affect the difficulty if it is chosen on the basis of accessibility and quality of visualization. The major difficulties were apparently related to the maternal obesity, resulting in poor sonographic image; the active fetal movement, and the presence of polyhydramnios, making puncture site more difficult to access.

Limitation of the present study, the model may not represent the real practice in several ways. For example, the authors did not often have the umbilical cord at 18-22 weeks of gestation, the authors usually got the cord at term. Therefore, the presented model practice might have not truly simulated the real practice, which the cord was smaller at 18-22 weeks of gestation. Additionally, the skill developed during the period of study may not be gained solely from the model, because the trainee also practiced amniocentesis in the same time. Moreover, the trainee acted as an assistant in the operating field from time to time during the training period.

The limitation of the present study is that there was no control to compare the time consumed between the trainee who practiced with model and one who did not. The procedure-related fetal loss should be considered the best outcome of interest, however, this variable rarely occurred and the present study did not have enough sample size to gain power for such an answer.

Finally, the present study included only one trainee. The authors can not expect that the impressive result like this can be reproduced by other situations. Therefore, this training cthe authors'se can suggest the benefit of the training, more several trainees are needed to test the efficacy.

Conclusion

Cordocentesis model is simple, inexpensive but effective for the beginning practitioners to develop their experience and skill in cordocentesis. Without any fetal and maternal jeopardy, this could be a useful practical instrument to promote the success rate and lower the complications of the invasive fetal blood sampling. However, the reduction of fetal loss rate with the training program remains to be further tested.

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ประสบการณ์การเจาะเลือดสายสะดือทารกในครรภ์จำนวน 50 ราย ภายหลังการฝึกหัดกับหุ่นจำลอง

เฟื่องลดา ทองประเสริฐ, ธีระ ทองสง, ชเนนทร์ วนาภิรักษ์, สุพัตรา ศิริโชติยะกุล, วีรวิทย์ ปิยะมงคล, พฤหัส จันทร์ประภาพ

วัตถุประสงค์: *เพื่อรายงานประสบการณ์ของผู้วิจัยในการเจาะเลือดสายสะดือทารกในครรภ์จำนวน 50 ราย ภายหลังจากฝึกเจาะเลือดสายสะดือทารกในครรภ์ด้วยหุ่นจำลองจำนวน 300 ครั้ง*

วัสดุและวิธีการ: *หุ่นจำลองเพื่อฝึกเจาะเลือดสายสะดือทารกในครรภ์ประกอบด้วยตู้กระจกสำหรับบรรจุน้ำและฝาปิดทำจากยางพาราซึ่งคลุมซ้ำอีกครั้งด้วยหนังหมูเพื่อจำลองลักษณะหน้าท้องหญิงตั้งครรภ์ การเตรียมสายสะดือทำโดยฉีดสีเมอร์คิวโรโครมเข้าไปในเส้นเลือดสายสะดือขนาดยาว 30 ซม. จนเต็ม ผูกปลาย 2 ด้านแล้วนำไปแขวนในตู้กระจก กำหนดให้ผู้วิจัยฝึกเจาะเลือดสายสะดือทารกในครรภ์โดยใช้เครื่องตรวจคลื่นความถี่สูงชี้นำปลายเข็มเจาะช่องไขสันหลังไปยังสายสะดือทารกเพื่อดูดสีภายในคล้ายการปฏิบัติจริงรวมทั้งหมด 300 ครั้ง (วันละ 20 ครั้ง เป็นเวลา 15 วัน) หลังจากผู้วิจัยทำการฝึกเจาะเลือดสายสะดือทารกในครรภ์ด้วยหุ่นจำลองครบตามกำหนดแล้ว ให้ผู้วิจัยทำการเจาะเลือดสายสะดือทารกหญิงตั้งครรภ์อยู่ในช่วง 18 ถึง 22 สัปดาห์ที่มารับบริการตรวจวินิจฉัยก่อนคลอด ณ โรงพยาบาลมหาราชนครเชียงใหม่ ระยะเวลาในการทำหัตถการแต่ละครั้งกำหนดไม่นานเกิน 30 นาที และต้องมีอาจารย์แพทย์ผู้เชี่ยวชาญในการทำหัตถการคอยดูแลอยู่ใกล้เคียง หากผู้วิจัยไม่สามารถเจาะเลือดสายสะดือทารกในครรภ์ได้ภายในเวลาที่กำหนดให้ถือว่าหัตถการครั้งนั้นล้มเหลว ให้อาจารย์แพทย์ผู้เชี่ยวชาญเป็นผู้รับผิดชอบในการทำหัตถการต่อจนสำเร็จ การทำหัตถการแต่ละครั้งจะจดบันทึกระยะเวลาในการทำหัตถการ ตำแหน่งของสายสะดือที่เลือกเจาะ ตำแหน่งที่รกเกาะและภาวะแทรกซ้อนที่เกิดขึ้นเพื่อนำมาวิเคราะห์ทางสถิติต่อไป

ผลการศึกษา: *ผู้วิจัยได้ทำการเจาะเลือดสายสะดือทารกในครรภ์ของหญิงตั้งครรภ์จำนวนทั้งหมด 50 ราย พบว่าอัตราความสำเร็จของหัตถการภายใน 30 นาทีเท่ากับร้อยละ 100 โดยหัตถการส่วนใหญ่ใช้ระยะเวลาไม่เกิน 10 นาที (ร้อยละ 92) ภาวะแทรกซ้อนที่พบได้บ่อยคือ ภาวะเลือดออกจากรอยเจาะบริเวณสายสะดือ (ร้อยละ 30) และภาวะหัวใจทารกเต้นช้าลง (ร้อยละ 8) แต่พบว่าเป็นเพียงภาวะแทรกซ้อนที่พบได้ชั่วคราวเท่านั้น*

สรุป: *การฝึกเจาะเลือดสายสะดือทารกในครรภ์ด้วยหุ่นจำลองเป็นการเพิ่มพูนทักษะและความชำนาญในการทำหัตถการให้กับสูติแพทย์ที่เริ่มฝึกหัดการเจาะเลือดสายสะดือทารกในครรภ์ได้อย่างมีประสิทธิภาพ วัสดุอุปกรณ์สามารถหาได้ง่าย ราคาไม่แพง นอกจากนี้หญิงตั้งครรภ์และทารกในครรภ์ยังไม่ได้รับผลกระทบจากการฝึกหัด อย่างไรก็ตามการฝึกเจาะเลือดสายสะดือทารกในครรภ์ด้วยหุ่นจำลองนี้ยังต้องการการทดสอบถึงประสิทธิภาพในการลดอัตราการสูญเสียทารกในครรภ์ต่อไป*