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Randomised experimental comparison of 23G versus 22G needle for ultrasound guided invasive fetal procedures

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Abstract

Objectives: To experimentally compare the standard 22G spinal needle with a newer 23G needle with specific ultrasound visualisation tip (Cook echotip®, Spencer, Indiana, USA) in the setting of ultrasound-guided invasive intrauterine procedures.
Materials and Methods: We first determined the size of the defects created in human fetal membranes using light microscopy and adapted area calculating software by both needles in an *in vitro* model performing 20 paired experiments on 4 term membrane specimens. Secondly, we determined the performance of 3 groups of operators, with different levels of experience in invasive intrauterine procedures during cordocentesis on a simulator model, using either a 22G or 23G needle. For each procedure, we measured the time required to successfully obtaining 2 ml of artificial blood in 24 paired experiments.
Results: The mean ± SD defect sizes created was 0.66 ± 0.12 mm^2 with the 22G needle and 0.59 ± 0.13 mm^2 with the 23G needle (P = 0.11). The mean duration of sampling was 144 ± 188 sec with the 22G needle versus 140 ± 120 sec with the 23G needle (P = 0.99) for all operators pooled but four out of six operators showed shorter sampling times with a 22G needle.
Conclusion: This experimental study shows that the use of a 23G needle compared to a 22G needle was not associated with significantly different procedure duration or defect size.

Key words: Fetus, ultrasound, amniocentesis, fetal membranes, fetal surgery.

Introduction

Amniocentesis for prenatal karyotyping is today the most frequently performed invasive intrauterine procedure (Eisenberg and Wapner, 2002), but still carries a procedure related risk for amniotic fluid leakage estimated to be approximately 1-2% (Reece, 1997; Tabor *et al*., 1986). Postprocedural amniotic fluid leakage is the strongest predictor of subsequent fetal loss (Saltvedt and Almstrom, 1999). Instrument size influences the created defect in the fetal membranes and the subsequent risk for amniotic fluid leak and miscarriage. Traditionally, 20 and 22G spinal needles have been used for amniocentesis, although remarkably, this was not based on experimental data. More recently, a new needle was designed and marketed specifically for invasive intrauterine procedures (23G: Cook echotip®, Spencer, Indiana, USA). This smaller 23G needle potentially represents less trauma to the uterus and fetal membranes. Additionally, the specifically designed tip (echotip®, Fig. 1) is designed to enhance ultrasound visualisation and could reduce the sampling time, and therefore the discomfort for the patient and risks of the procedure. The aim of this study was to compare this new needle type with a standard 22G spinal needle in terms of defect size created in the fetal membranes and time needed to perform an invasive intrauterine procedure.

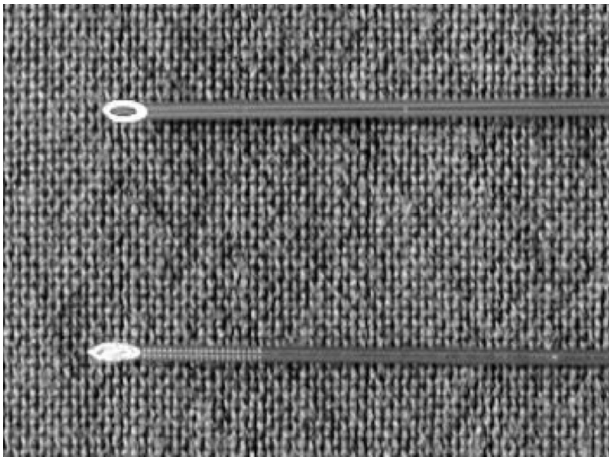

Fig. 1. *— Above: 22G needle. Below: 23G echotip® needle*

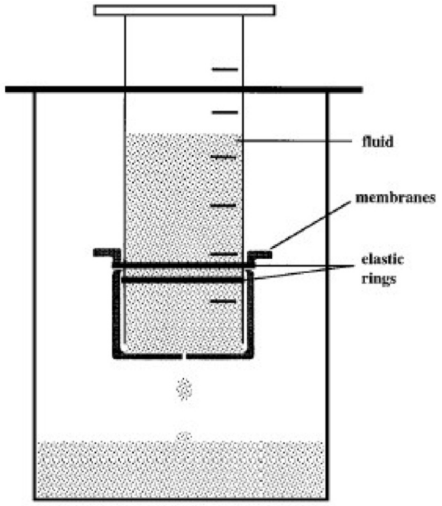

Fig. 2. *— Ex vivo* model for amniocentesis using human fetal membrane patches secured to the bottom of a plastic tube. The membranes can be punctured and the flow rate through the defect quantified. Reproduced with permission from Louis – Sylvestre *et al*. (1997).

Materials and methods

Fetal membranes were freshly obtained from four women delivered by elective caesarean section at term (37-40 weeks) following uncomplicated pregnancies. Membrane patches of 100 × 50 mm were excised and divided in two equal parts. Each membrane patch was wrapped around the bottom of a plastic tube and secured with an elastic ring. The tube was fixed in a vertical position and then filled with Hartmann's solution or amniotic fluid at 37°C (Fig. 2). The fluid pressure was kept constant at 15 cm H_2O representing a physiologic value for amniotic pressure in pregnancy (Fisk *et al*., 1992). The membranes were punctured by introduction of the needle at an angle of 90º 1 to 1.5 cm deep through the bulging membranes using either a 22G or 23G needle. The characteristics of the needles used are described in Table 1. The duration of the puncture was 1 second. After the experiment, the membrane was detached and the wound edge stained with India ink to facilitate recognition during microscopic evaluation. We calculated the size (mm^2) of the defect using a microscope (Zeiss, Oberkauchen, Germany), at magnification (20×) and adapted software (KS 100 3.0, Carl Zeiss, Oberkochen, Germany). In cases where sliding of the amnion and chorion against each other had resulted in a smaller net defect, this net defect through both the amnion and chorion, was measured.

As a second part of the study, we determined the performance of six operators with different levels of clinical experience [novice (N = 2), intermediate (N = 2), expert (N = 2)], using either a 22G or 23G needle for cordocentesis in a randomised video-controlled setting (Silver *et al*., 1998). The needle type was determined before each procedure by randomisation (sealed envelopes). All procedures were performed on a cordocentesis simulator (Limbs & Things Ltd, Bristol, United Kingdom). This simulation model allows for the combination of realistic ultrasound visualisation as well as mock blood sampling from an anterior or posterior placenta with umbilical cord (Fig. 3). Ultrasonography was performed using the same machine we use for all our invasive intrauterine procedures, an Acuson Sequoia (Mountain View, Ca) with a 2.5-6 MHz transducer. Each operator performed four cordocentesis procedures (single operator, two hands technique) with each needle. In total, 24 procedures were performed with each needle. Each operator performed only one procedure per day. For each procedure, we measured the procedure time, defined as the time from puncturing the cordocentesis simulator to successfully

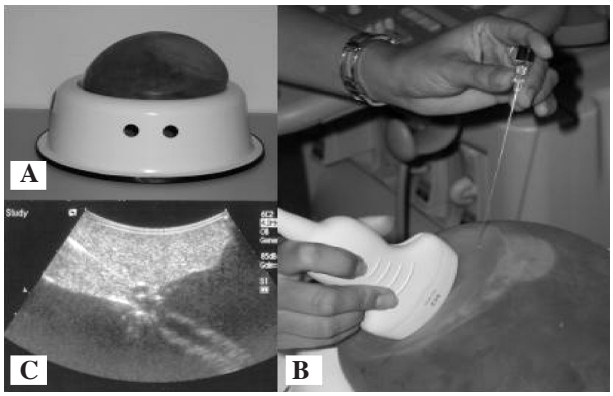

Fig. 3. *—* A: Limbs & Things model
B: Puncturing the model with ultrasonographic guidance
C: The ultrasound image. The needle traverses the placenta; the needletip is in the umbilical cord insertion.

Table 1. — Characteristics of needles used and comparison of actual and theoretical defects created in the fetal membranes by the different needles (mean ± SD).

	22G	23G	P
Outer diameter (mm)	0.70	0.60	–
Theoretical defect* (mm^2)	0.39	0.29	–
Measured defect (mm^2)	0.66 ± 0.12	0.59 ± 0.13	0.11

22G: Vygon, Valkenswaard, The Netherlands
23G: Cook echotip®, Spencer, Indiana, USA
*Calculated as the cross-sectional area, based on the outer diameters provided by the manufacturer.

collecting 2 ml of artificial blood, in seconds. We therefore recorded each procedure on video. After completion of the project, measurement of the procedure-times was performed from the videotapes by two co-workers blinded to the type of needle that was used during the experiment.

Results were stored and analysed using SPSS 10 (SPSS Inc., Chicago, Illinois) software and are expressed as Mean ± SD. Means were compared using Students' t-test. P = 0.05 was taken as the limit of significance.

Results

The expected and actual defects created by both 22G and 23G needles are shown in Table 1. The defect sizes created by 22G needles were slightly larger than those created by 23G needles: 0.66+/-0.12 versus 0.59+/-0.13 mm^2. However, this difference was not significant (P = 0.11). In accordance to previous observations, the defect size created by both needles was larger than the expected defect size based on the cross-sectional diameter of the needle (Devlieger *et al*., 2002).

The mean sampling duration for all operators pooled was similar: 144 ± 188 sec with a 22G needle versus 144 ± 120 sec with a 23G needle, P = 0.99. The mean duration of sampling for the different study groups is shown in Table 2. There were no significant differences in duration of sampling between the two needles in the three study groups, however, 4 of the 6 operators required less time for cordocentesis with the 22G needle as compared to the 23G needle.

Discussion

Despite the increasing number of pregnant women undergoing invasive intrauterine procedures and the not infrequent, potentially dramatic complications, few experimental studies have focused on the technical aspects of these procedures.

As a general rule, to reduce the risks of intrauterine procedures, it seems logical to use the least traumatic needle that combines fast sampling and easy ultrasound visualisation. In today's clinical practice, most fetal medicine specialists use 22G spinal needles to perform amniocentesis (Eisenberg and Wapner, 2002). We have shown that this needle creates a small defect in the fetal membranes reducing subsequent fluid leakage, as compared to bigger needles (Devlieger *et al*., 2002). Smaller needles with a diameter of 24G and 26G are associated with increased sampling time, which results in relatively larger defects, probably as a result of increased manipulation and physiologic tremor (Devlieger *et al*., 2002). Additionally, these very thin needles can be blocked by particles in amniotic fluid leading to unsuccessful sampling. Larger needle diameters are associated with slightly shorter sampling time, but exponentially larger defects in the fetal membranes (Devlieger *et al*., 2002). Therefore, a 22G needle appears to provide a good compromise between sampling time and defect size. Only recently, needle

Table 2. — Mean duration of sampling (± SD) for the different study groups using a 22G or a 23G needle.

	22G	23G	P
Expert (N = 2)	137 ± 223	153 ± 148	0.87
Intermediate (N = 2)	201 ± 210	141 ± 117	0.49
Novice (N = 2)	94 ± 92	139 ± 108	0.39
Pooled (N = 6)	144 ± 188	144 ± 120	0.99

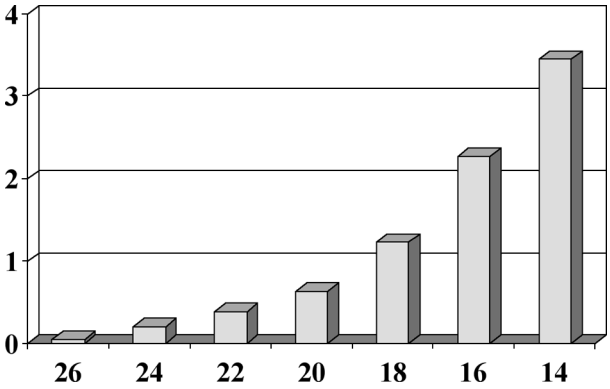

Fig. 4. — Theoretical defects (mm^2) created in fetal membranes by needles of different sizes.

diameters, shape and ultrasonographic properties have been designed and adapted specifically for invasive intrauterine procedures, especially amniocentesis. The 23G needle with echo-tip® has several theoretical advantages, but these were not confirmed in this experimental study.

First, the specially designed echotip was expected to give a better ultrasonographic image than the needles currently used. This should help the operator in determining the location of the needle inside the amniotic sac and lead to a decrease in sampling time. However, most operators did not have shorter sampling times with the 23G needle, on the contrary: 4 out of 6 operators performed better with the 22G needle. In general, the oblique tip of a standard needle sufficiently enhances sonographic visualisation. The additional reflections created by the 23G echotip® not only seem unnecessary, but may even have a negative effect on precisely localizing the needle tip. A possible limitation of our study could be the use of both an excellent ultrasound machine and a good model; we cannot exclude that the echotip® could be of more value with the use of less advanced equipment or in procedures done in obese patients.

Secondly, the defect created by the 23G needle was not significantly smaller than the fetal membrane defect created with a 22G needle. Theoretically, the cross-sectional area of the needle determines the minimal size of the created defect. This cross-sectional area relates to the needle diameter according to the equation πr^2. Therefore, the relationship between needle diameter and defect size can be expected to be exponential (Fig. 4). Defects created by both 22G and 23G needles are in the horizontal part of this exponential curve (Devlieger *et al*., 2002), explaining the small differences measured. Of course, the relatively small sample size used in this study could also contribute to the fact that no significant difference was noted in our experiments.

Using the cordocentesis model however has a few limitations. There are only two different placentas with one anterior and one posterior cord insertion. Therefore, operators may get to know the model after a few procedures. Also, procedures performed on the model are not complicated by a moving fetus and complications like PROM do not occur. Nonetheless, with the blinded randomised design, we would not expect the results of our study to be different if performed in the actual clinical setting.

In summary, a 23G needle with adapted tip for enhanced ultrasound visualisation did not, in comparison with a 22G spinal needle, result in decreased defect size in the fetal membranes or decreased sampling time in a randomised experimental setting. Therefore, the claimed advantages of the more expensive 23G needle over the 22G needle are not supported by our study.

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