Instruments & Methods

Development and initial experience with a manually controlled spring wire device ("cordostat") to aid in difficult funipuncture

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Funipuncture has evolved as a useful tool in prenatal diagnosis and treatment. The ease with which it can be performed depends on placental implantation site, amniotic fluid volume, fetal presentation and activity, gestational age, and operator experience. Under select circumstances, such as hydramnios, oligohydramnios/anhydramnios, a back-up fetus/posterior placenta, or gestation of fewer than 20 weeks, funipuncture can be difficult or impossible. We have developed a new instrument, the "Cordostat," which can help the operator perform difficult funipuncture by providing stabilization and allowing intrauterine manipulation of the umbilical cord. The instrument consists of a deflecting wire guide threaded through a 19.5-gauge trochar needle, which can be manually controlled to coil around and stabilize a free loop of cord. Conventional funipuncture can then be performed through a second uterine puncture. We describe use of this instrument in 12 patients undergoing second-trimester induced abortion. ***(Obstet Gynecol 77:471, 1991)***

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Funipuncture has become the method of choice for obtaining safe access to the fetal circulation for a variety of diagnostic and therapeutic indications.[1,2] Under optimal circumstances, the umbilical cord is punctured at its most stable position, which in most cases is the placental insertion site. Alternatively the cord can be entered at the fetal insertion site.[1,2] Puncturing an unstable free loop of cord is more difficult technically but is often the only safe access to the fetal circulation. We have designed, and are currently using selectively, a manually controlled spring wire device we have named the "Cordostat," which stabilizes a free loop of cord and safely allows funipuncture. This report describes the instrument's design and our initial experience with its use in second-trimester pregnancies before induced abortion.

Materials and Methods

The Cordostat was developed by serial modifications of a urologic deflecting wire (Cook Urologic, Inc., Spencer, IN). An instrument designed by Cohen et al (presented at the Congress de Societe Internationale Urologica, San Francisco, California, 1982) for ureteral exploration was modified specifically for the purpose of grasping the umbilical cord. The instrument is constructed of medical-grade 300 series stainless steel. Specific modifications include a 3-cm tip deflection arc, 3-cm deflection tip length, a wire guide 43 cm long with a 0.028-in diameter, and a full deflection arc of 360° to form a gripping loop. The trochar needle is 12 cm long and has a 19.5-gauge diameter. A needle depth marker (Tuohy-Borst valve; Cook Urologic, Inc.) commonly used in invasive radiology was adapted as a wire guide depth marker. The handle is constructed of medical-grade plastic modified with a stainless-steel brake (lock) apparatus, which allows manual locking and release of the wire coil.

The described structural modifications resulted from ten uncomplicated sequential studies in three near-term baboon gestations. The instrument was modified after each experience to allow better control of the deflecting wire loop. The primary author (MRF) worked directly with the engineers at Cook Urologic Inc. to implement design modifications after each application.

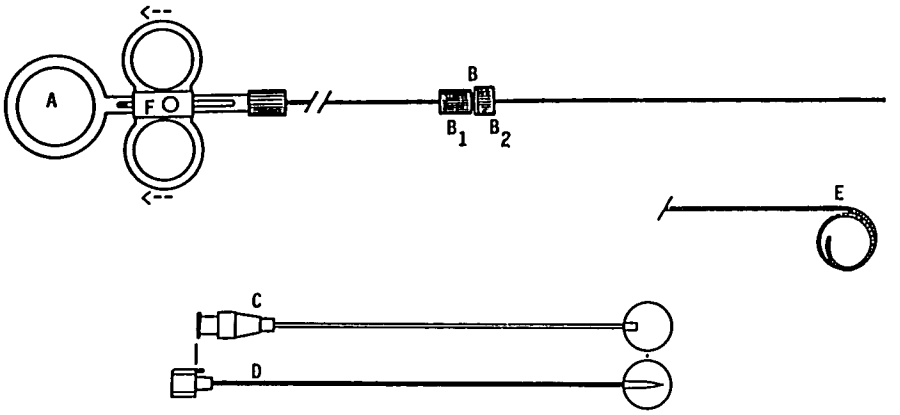

Figure 1. The Cordostat with its components labeled (see text). The wire guide (E) is depicted in the "flexed mode."

When modifications were complete and we became adept in using the Cordostat in the baboon fetus, we obtained approval from the University Hospitals Human Subjects Committee to begin trials in human pregnancies before second-trimester induced abortions. Our initial experience consisted of 12 women between 16–24 weeks' gestation undergoing intrauterine prostaglandin-urea injection for elective abortion of a severely malformed fetus. After obtaining written informed consent, we began the procedure by performing a real-time ultrasonographic survey using a General Electric (Milwaukee, WI) 2600 ultrasound machine with a 5-MHz curvilinear transducer to confirm the specific fetal malformation and estimate gestational age. The placental implantation site was noted and the umbilical cord width was measured carefully. The insertion site for the Cordostat trochar was marked on the maternal abdomen. A midline approach that would avoid the placenta and provide access to the majority of the umbilical cord loops (both to the patient's left and right) proved to be the most successful.

The Cordostat (Figure 1) is intended for one-time use and is packaged with all of its components as a sterile unit. The package is opened and the wire guide (E) is placed through the hole in the depth marker (B), as shown in Figure 1. The wire guide is depicted in the "flexed mode," obtained by squeezing A in the direction shown by the arrows (allowing F to lock). When released (unlocking F), the wire guide (E) straightens, reflecting the inherent memory of the spring wire ("relaxed mode"). The curling motion of the spring wire, obtained by manually squeezing A (relaxed mode to flexed mode), allows gentle grasping and manipulation of the umbilical cord in utero. The wire guide (E) is then threaded through a 19.5-gauge trochar (C), and a length of spring wire is allowed to protrude beyond the distal end at a length approximately twice the sonographically measured width of the umbilical cord. When that length is achieved, the distal section of the depth marker (B2) is attached to the trochar with a Luer lock (C), and the proximal section (B1) is tightened to secure it to the wire guide (E). This process allows only a fixed length of wire to extend beyond the trochar and permits the operator to turn the coil left and right in utero by turning the trochar. For cases in which the 12-cm trochar fails to reach the umbilical cord (ie, severe hydramnios), the length of the wire guide can be increased by threading an additional length through the trochar, allowing cord manipulation at virtually any depth.

After confirmation of a working intravenous line, the maternal abdomen is prepped with iodine solution. Under sterile conditions and appropriate local anesthesia (10–20 mL of 1% lidocaine), the needle/trochar unit (C and D) is directed, under ultrasound guidance, to the desired area of the intrauterine space near a free loop of umbilical cord. The needle (D) is removed from the trochar (C) and the wire guide (E) is threaded up to the depth marker (B) and locked in place. The wire guide (E)/trochar unit (C) is directed toward a free loop of cord. The wire loop (E) is directed manually to gently coil or hook a free loop of cord by squeezing (A) and rotating the trochar (C) (Figures 2A and 3). Once the cord has been secured, the entire unit (B, C, E) is pulled upward or outward to move the cord to the uterine wall, allowing easier access for funipuncture (Figure 2B). The apparatus (A) is then handed to an assistant, who maintains sterile conditions and stabilizes the trochar. The operator performs a free-hand funipuncture through a second puncture site, directing a 22-gauge needle to the secured free loop of cord. Following funipuncture, the wire guide loop is relaxed (unlocking F) and removed from the trochar. Finally, before removal of the trochar, prostaglandin and urea are injected intra-amniotically under direct ultrasound visualization.

In each of our procedures, successful funipuncture

was confirmed by fetal blood mean corpuscular volume analysis, bedside APT testing, or saline flush into the umbilical cord after sampling. Each patient was closely evaluated for procedure-related complications by vital sign assessment every 15 minutes for 2 hours after the intra-amniotic injection. Following delivery, the fetus, placenta, and umbilical cord were inspected visually by a junior resident and evaluated grossly and microscopically by an attending pathologist for evidence of trauma due to instrumentation.

Results

In all 12 patients, intrauterine grasping and manipulation of the umbilical cord by the Cordostat was successful (Table 1). Funipuncture after cord stabilization was successful in nine of the 12 patients. In one patient (DL), the procedure was not attempted because of patient anxiety. In the other two failures (MC and JA), funipuncture was attempted but fetal blood sampling was unsuccessful. In MC, anhydramnios forced us to abort the procedure after one failed attempt. In JA, maternal obesity (306 lb) and a lateral abdominal approach contributed to procedure failure. The Cordostat was introduced laterally in an attempt to isolate what appeared to be many redundant coils of umbilical cord. When an attempt was made to perform funipuncture after stabilizing a free loop, the fetus rolled over, pulling the cord free from the wire loop and over to the opposite side of the uterus. We were unable to proceed. The specific problems we experienced with lateral placement of the Cordostat have convinced us that a midline (versus lateral) approach is best and offers more flexibility in terms of cord accessibility should the fetus move or roll over. The difficulties encountered in patients MC and JA were primarily related to our technical learning curve. As we became more experienced with use of the instrument, both our success rate and procedure time improved.

In patient DL, funipuncture was not attempted. The patient was extremely anxious about the pregnancy loss, and an inordinate amount of time was needed to grasp and manipulate the cord (20–25 minutes) because of both maternal obesity and our initial inexperience. The average amount of time required to place the Cordostat and perform successful funipuncture ranged from 5–25 minutes, with our earlier attempts requiring up to 25 minutes. More recently, with patients 8–12, the average procedure time has been reduced to approximately 5 minutes. There were no maternal complications encountered, and post-

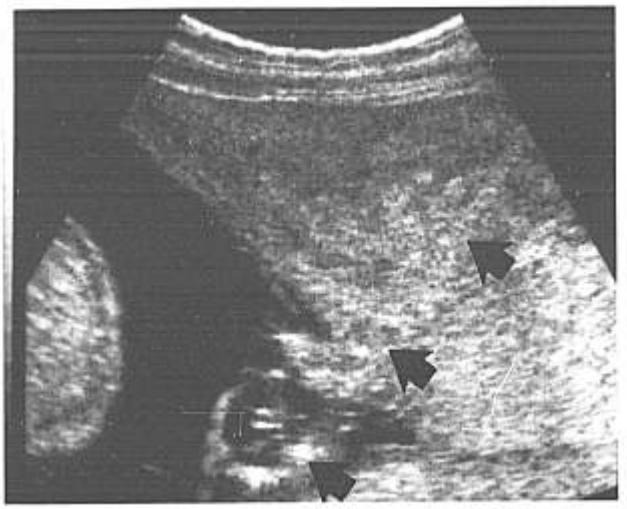

Figure 3. The Cordostat (*arrows*), moving from right to left, grasps the umbilical cord in utero (cord is within loop).

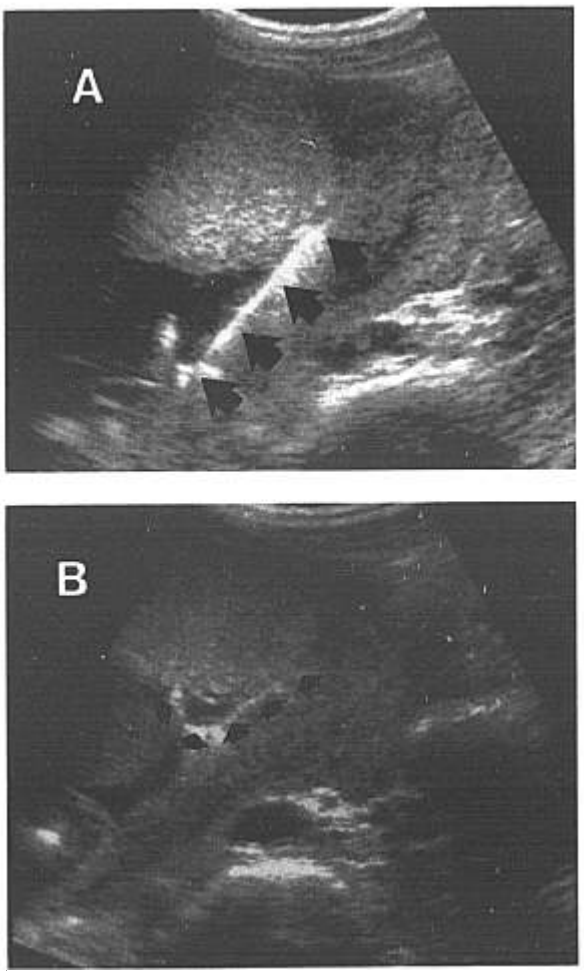

Figure 2. The Cordostat is visualized in the amniotic cavity under high-resolution ultrasound. A) The Cordostat (*arrows*), in the flexed mode, has been manipulated to grasp the umbilical cord (seen within the hook). B) The Cordostat has been retracted to stabilize the cord anteriorly.

Table 1. Patient Characteristics

Patient	Fetal diagnosis	Gestational age (wk)	Placental location	Amniotic fluid volume	Cord grasping/ manipulation	Funipuncture	Comments
1) MC	Renal agenesis	18	Fundal	Reduced	Yes	No	Anhydramnios
2) JA	Anencephaly	20	Posterior	Increased	Yes	No	Fetus rolled, maternal obesity, lateral abdominal approach
3) DL	Anencephaly	18	Anterior	Normal	Yes	No	Maternal anxiety and obesity
4) AS	Neural tube defect	23	Fundal	Normal	Yes	Yes	None
5) BS	Cystic hygroma, hydrops	21	Fundal	Reduced	Yes	Yes	None
6) KW	Cystic hygroma, hydrops	17	Anterior	Normal	Yes	Yes	None
7) LP	Neural tube defect, ventriculomegaly	18	Post-fundal	Increased	Yes	Yes	None
8) LM	Down syndrome	21	Posterior	Normal	Yes	Yes	None
9) CF	Meckel syndrome	18	Anterior	Reduced	Yes	Yes	None
10) LH	Neural tube defect, ventriculomegaly	20	Posterior	Normal	Yes	Yes	None
11) JJ	Multiple anomalies, trisomy 13	24	Posterior	Reduced	Yes	Yes	None
12) CS	Cystic hygroma, hydrops	16	Fundal	Normal	Yes	Yes	None

delivery pathologic evaluation of the fetus, placenta, and umbilical cord in all patients failed to reveal any gross or microscopic evidence of trauma induced by cord instrumentation.

Discussion

Funipuncture as a method of prenatal diagnosis and/or treatment has become popular throughout the world. The technical aspects of the procedure, under most circumstances, are not extremely difficult and can be performed easily by the experienced operator. The most recent information from the National PUBS Registry (Philadelphia, PA) indicates that 5280 funipunctures have been performed (through July 1990) with a single-puncture success rate of 94.2%; 5.8% required two or more uterine punctures. Funipuncture was reported to be more successful if the primary site for blood sampling was the placental root as compared with a free-floating loop of cord.

Most funipunctures can be accomplished quite readily when the fetus is 22 or more weeks' gestation, the placenta is anterior, the amniotic fluid volume is normal, and the fetus is cooperative and relatively inactive. The Cordostat was developed specifically to aid in funipuncture and/or fetal intravascular transfusion when circumstances are less than ideal. For example, accessing the fetal circulation at 16–18 weeks' gestation in the presence of hydrops or hydramnios is difficult and may require more than one attempt. Similarly, a back-up presentation obscuring a posteriorly implanted placental cord insertion site combined with severe oligohydramnios or anhydramnios makes funipuncture extremely difficult.

Avoiding transplacental funipuncture in patients with Rh isoimmunization theoretically may reduce iatrogenic worsening of the disease by reducing transplacental bleeding. Fetal paralysis via intramuscular pancuronium has been suggested to aid in safe funipuncture by reducing fetal activity. However, using fetal paralysis and/or the abdominal cord insertion site may result in additional procedure-related risks.[3,4]

As stated above, suboptimal conditions may require more than two uterine punctures to perform funipuncture successfully. The need for two punctures is an obvious inherent limitation of the Cordostat. The proposed advantage of this instrument involves cases in which the operator anticipates a difficult procedure requiring two or more uterine punctures. Use of the Cordostat limits the number of punctures to only two

in most circumstances. In addition, when the operator is having difficulty accessing the cord after one needle insertion, the 19.5-gauge Cordostat could be inserted to manipulate the cord into the path of the primary needle. We acknowledge that a 19.5-gauge trochar theoretically may increase the risk of pregnancy loss over that with a 20- or 22-gauge trochar; however, our experience suggests that the risk is low.[1] Reduction of the caliber of the Cordostat in an attempt to address the theoretical risk inherent with a large-caliber trochar substantially reduced the utility and grasping capability of the instrument. Current advances in metal technology, however, indicate that it is only a matter of time until the needle caliber can be reduced without compromising the strength and maneuverability of the wire guide.

The Cordostat is a potentially valuable tool that can provide the operator safe access to the cord on those occasions when conventional funipuncture is anticipated to be difficult or impossible. Our initial experience suggests that the Cordostat warrants further clinical evaluation.

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AN IMPROVED SPIRAL ELECTRODE APPLICATOR SYSTEM FOR FETAL HEART RATE MONITORING

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A new fetal scalp electrode applicator system uses a guide tube with increased curvature and a plunger mechanism to advance, rotate, and release the spiral electrode. Results of a preliminary survey among house staff who used the system in 51 patients indicated a favorable impression, with 96.1% of the applications rated as "much better," "better," or "same" as compared with the conventional system. The rate for a subset of 26 patients with limited cervical dilatation (1–3 cm) or high station of the presenting part (−1 to −3) was similarly good (92.3%). The characteristics found most favorable were the increased curvature for facilitating applications to high presenting parts, the plunger mechanism for applying the electrode, and better control of the guide tube. ***(Obstet Gynecol 77:475, 1991)***

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The currently used spiral fetal scalp electrode system was introduced in 1972[1,2] and has since been widely used for intrapartum fetal heart rate monitoring. Although it has been useful in most obstetric situations, electrode application is difficult when the cervix is in a posterior position and minimally dilated and the presenting part is high. Under these circumstances, the applicator tip must be directed sharply upward in order to reach the presenting part. To accomplish this, the operator is often forced to bury his or her elbow and forearm in the patient's bed, assuming a position that is neither elegant nor practical.

To address some of these difficulties, a new electrode applicator system was devised that uses a guide tube with an increased curvature and a plunger mechanism that converts the longitudinal motion of the plunger rod into a rotational motion of the electrode carrier (Figure 1). We present the impressions of postgraduate trainees on the use of the new electrode applicator system.

Materials and Methods

The new applicator system comprises a plunger, an electrode carrier assembly, and a guide tube with an