

New lead for in utero pacing for fetal congenital heart block

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Complete heart block occurs in 4% to 15% of cases of fetal arrhythmia. Although it is usually well tolerated in the absence of complicating cardiac anomalies, as many as 25% of these fetuses have hydrops and die in utero.¹ The pathophysiologic arguments for fetal ventricular pacing are compelling. We describe the case of a fetus presenting with complete heart block, hydrops, and associated structural heart defects, the mother of whom consented to attempts at in utero pacing. The purpose of this article is to describe a new lead for percutaneous implantation that minimizes surgical trauma to both the fetus and the mother.

Clinical Summary A 36-year-old woman was referred to the Institute of Cardiology Porto Alegre at 18 weeks' gestation with a fetus presenting with complete heart block (heart rate, 47 beats/min), marked hydrops, left atrial isomerism, and an atrioventricular septal defect. Maternal therapy with positive chronotropic drugs and steroids did not reverse the low output failure and low fetal heart rate. A follow-up maternal ultrasound examination at 24 weeks' gestation suggested decreased right ventricular contractility in the fetus and abdominal and pleural effusions.

With the risk of fetal demise approaching 100%, fetal pacing was considered. After extensive discussions with the physicians involved with the Fetal Cardiology Research Program of the Heart Institute University of São Paulo and the Institute of Cardiology Porto Alegre, including explanation of the procedure's benefits and risks, the patient consented to attempts at in utero transthoracic fetal ventricular pacing. The procedure was performed at 25 weeks' gestation according to a protocol approved by our institutional ethics committee on human research.

Anesthesia. The mother was sedated with intravenous midazolam and fentanyl citrate. Xylocaine 1% was infiltrated

subcutaneously in her abdomen in preparation for choriodocentesis. The placental cord was then punctured transplacentally, under ultrasonographic guidance, with an 18-gauge needle. Pancuronium and ketamine were administered to the fetus.

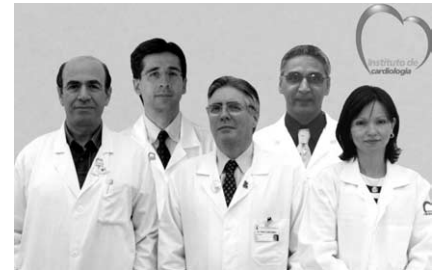
The new lead. We recently designed a prototype T-shaped lead that can be introduced through an 18-gauge needle to fix securely to the fetal myocardium, with no need for open surgical procedures. The lead represents a modification of the temporary epicardial pacing lead commonly used after heart surgery. The main difference is that at the cardiac end, the pacing lead is cut close to the polypropylene coating, and a stainless-steel bar (5 mm × 0.5 mm) is connected to the wire, producing a T-bar. The purpose of this shape is to keep the new lead securely anchored to the myocardium, thus preventing lead dislodgment. The other end of the lead remains intact, consisting of a long straight needle. The lead length remained the original 60 cm.

In the present case the new pacing lead was driven to the heart of the fetus through the tip of a specially designed, 15-cm, 18-gauge introducer needle with a 25° beveled tip. This tip contained a 7-mm longitudinal side slot cut from the heel of the bevel that housed the T-bar. The T-bar was positioned within the lumen at the tip of the needle, and the pacing wire protruded from the slot and trailed alongside the needle (Figure 1). Use of a needle stylet was planned to eject the T-bar from the slot.

Fetal pacing procedure. The site for lead introduction was marked on the mother's abdomen, and local anesthesia was applied. Under continuous scanning, the new lead was inserted into the uterine cavity and advanced into the fetal thorax and then the ventricle. The fetus was in the dorsal presentation, making it difficult to reach the ventricles. After 4 attempts, the needle tip hit the myocardium. The needle stylet was gently advanced into the needle lumen, and the T-bar lead was ejected from the introducer needle slot into the myocardium by pressing the needle stylet forward. The introducer needle was then withdrawn. A second lead was placed in the thoracic wall for bipolar stimulation. The leads were then connected to the pacing system analyzer (Biotronik ERA 300; Berlin, Germany) to measure the sensitivity and stimulation thresholds. Ventricular pacing was begun at 140 beats/min. Stimulation resistance was measured during



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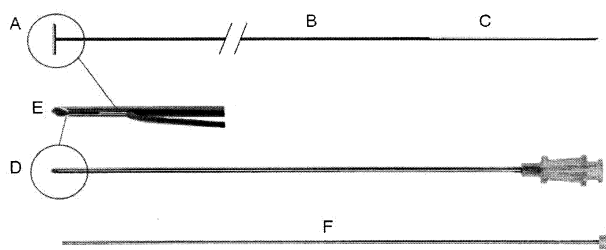


Figure 1. The introducer needle with the new T-bar lead: **A**, stainless steel bar; **B**, pacing wire with polypropylene coating; **C**, straight needle; **D**, 18-gauge introducer needle with a 25° beveled tip fashioned with a 7-mm longitudinal side slot cut from the heel of the bevel (**E**); **F**, needle stylet.

constant-voltage pacing (5 V) at a pulse duration of 0.5 ms. We measured a stimulation resistance of 357 Ω and a sensed fetal R wave of 6.4 mV. During the procedure, cardiac tamponade developed, which was managed with pericardiocentesis.

Fetal myocardial stimulation threshold. Measurements were made at constant pulse width pacing until the lowest output provided 100% ventricular capture. Stimulation thresholds were obtained at pulse widths ranging from 0.1 to 2.0 ms by gradually decreasing the voltage output of the pulse analyzer to the point at which ventricular noncapture was apparent with bradycardia. The acute fetal myocardial stimulation thresholds were consistently low, with no stimulation failure seen with the new electrode. The curve remained relatively constant at pulse widths of greater than 0.6 ms, turning sharply upward with shorter pulse widths of less than 0.6 ms. After all measurements were completed, the leads were connected to a Biotronik Actros SR single-chamber pulse generator, which was implanted subcutaneously in the maternal abdominal wall. The pacemaker was set to the following parameters: VVI mode; pacing rate, 140 pulses/min; cardiac sensitivity, 1.25 mV; cardiac pulse amplitude, 5.0 V; and refractory period, 400 ms. During the first postoperative day, an echocardiogram revealed recovery of ventricular function, a stable fetal heart rate of 140 beats/min, and a mild pericardial effusion. No uterine contractions were observed during the postoperative period. Again, low stimulation thresholds and no stimulation failures were seen. Figure 2 shows the voltage strength-duration curves obtained during the procedure (ie, implantation) and on the first postoperative day. After 36 hours of ventricular pacing, asystole was noticed on ultrasonography, and the pericardial effusion appeared significant. The pregnancy was subsequently terminated through a cesarean section, resulting in the delivery of an 800-g hydropic infant.

Fetal Autopsy. Postmortem examination confirmed massive hydrops and cardiac anatomic defects. A moderate bloody effusion in the pericardial sac was considered the probable cause of fetal death. One pacing lead was firmly placed in the left ventricle's muscle, and the other lead was also placed in the thoracic wall. No hematoma was observed in the ventricular wall, nor were thrombi seen within the ventricles.

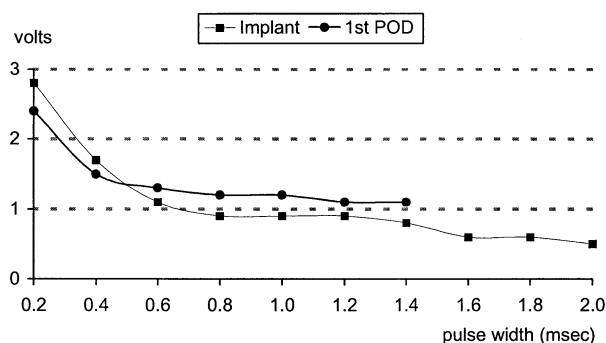


Figure 2. Voltage strength-duration curves for acute myocardial stimulation threshold of a human fetus during lead implantation (*implant*) and on the first postoperative day (*1st POD*).

Discussion

The T-bar lead proposed here for use in percutaneous fetal pacing might offer important technical advantages over leads used in conventional open surgical procedures. During the observed period of fetal pacing, our lead provided stable fixation with acceptable performance, as demonstrated by the low acute thresholds. Indeed, we believe that this is the first documentation of voltage strength-duration curves for the acute myocardial stimulation threshold of a human fetus that survived 36 hours after intrauterine pacemaker implantation. Moreover, this technique has the potential to minimize surgical trauma to both the fetus and the mother.

The cardiac tamponade observed in this case could have resulted from the 3 failed attempts at lead placement. We believe that use of fetoscopy in conjunction with ultrasonographic guidance would allow for a more controlled procedure in which the new lead could be more easily placed.² In addition, the development of improved materials, such as a thinner needle (20 gauge) and a bipolar pacing wire, could facilitate puncture of the fetal myocardium, thus decreasing the chances of such a complication.

In the present case the fetal heart rate abruptly increased from 47 to 140 beats/min with pacing. Nevertheless, bradyarrhythmia, with a heart rate 50% of the normal fetal rate, is well tolerated in the absence of complicating systemic abnormalities or placental insufficiency. Therefore, it seems to us that a gradual increase in the fetal heart rate would be more adaptive and could adequately augment the cardiac output as well. It also is unclear whether such a jump in the fetal heart rate could result in any acid-base imbalances caused by increasing myocardial oxygen consumption and cardiac output.

Previous attempts at in utero percutaneous pacing, either through a transthoracic approach¹ or through the inferior vena cava,³ have resulted in fetal demise a few hours after the procedure. A lack of myocardial fixation and consequent dislodgment of the percutaneous lead represents a major technical limitation of the percutaneous approach. Although the authors have demonstrated that the pacing wires can be satisfactorily positioned within the heart, they could not prevent dislodgment with resumption of fetal activity. Our new prototype lead has the length increased from 60 to 150 cm to avoid this problem. Attempts at direct pacemaker implantation through a cesarean section were undertaken at the University of California, San

Francisco,⁴ and at the Institute of Cardiology Porto Alegre, both of which were unsuccessful.

In our previous experimental study,⁵ we described the use of an epicardial modified screw-in lead to pace fetuses with complete heart block through a cesarean section as a safer and more reliable procedure. However, the possibility of premature labor still represents a challenge for fetal surgery.⁶ The percutaneous approach associated with this new lead for fetal ventricular pacing seems to be more compelling and less invasive. Moreover, it should be a relatively inexpensive, simple, and quick alternative to classic surgical placement of an epicardial lead.

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References

1. Carpenter RJ Jr, Strasburger JF, Garson A, Smith RT, Deter RL, Engelhardt HT Jr. Fetal ventricular pacing for hydrops secondary to complete atrioventricular block. *J Am Coll Cardiol*. 1986;8:1434-6.
2. Kohl T, Strumper D, Witteler R, Merschhoff G, Alexiene R, Callenbeck C, et al. Fetoscopic direct fetal cardiac access in sheep: an important experimental milestone along the route to human fetal cardiac intervention. *Circulation*. 2000;102:1602-4.
3. Walkinshaw SA, Welch CR, McCormack J, Walsh K. In utero pacing for fetal congenital heart block. *Fetal Diagn Ther*. 1994;9:183-5.
4. Silverman NH, Kohl T, Harrison MR, Hanley FL. Experimental fetal surgery in the animal model and in the human fetus. In: Imai Y, Momma K, editors. *Proceedings of the Second World Congress of Pediatric Cardiology and Cardiac Surgery*. Armonk (NY): Futura Publishing Co; 1998. p. 622-3.
5. Assad RS, Jatene MB, Moreira LF, Sales PC, Costa R, Hanley FL, et al. Fetal heart block: a new experimental model to assess fetal pacing. *Pacing Clin Electrophysiol*. 1994;17:1256-63.
6. Longaker MT, Golbus MS, Filly RA, Rosen MA, Chang SW, Harrison MR. Maternal outcome after open fetal surgery. A review of the first 17 human cases. *JAMA*. 1991;265:737-41.