A new generation of cardiac implantable devices, known as Closed Loop Stimulation pacemakers, are now utilized to reduce episodes of bradycardia, syncope, and tachycardia in pregnant women. The device functions differently than conventional pacemakers by responding to changes in the patient’s cardiac output and heart rate based on physiologic demands and acute mental stress. Increased metabolic demands, including physiologic stress often accompany pregnancy, labor, and delivery. The Certified Registered Nurse Anesthetist providing analgesia and anesthesia for the laboring patient with CLS pacemaker may encounter rapid changes in heart rates, initiation of pacing modes, and hypotension resulting from reduced cardiac outputs. The ability to differentiate and diagnose the causes of hemodynamic changes and provide appropriate interventions is essential to optimize maternal and fetal outcomes. This case report details the anesthetic management of a laboring twenty-five-year-old primigravida with an implantable CLS pacemaker secondary to a history of third degree heart block, cardiac ablation after supraventricular tachycardia, and seizures. The parturient experienced intermittent pacing after neuraxial analgesia. Anticipation of the CLS pacemaker’s response to the parturient’s physiological and emotional response during the labor process will be discussed including recommendations to optimize maternal and fetal outcomes.

Keywords: Epidural, neuraxial, pacemaker, pregnancy, seizure.
output regulation is a feature of the CLS pacemaker that provides a safety margin for changes in pacing thresholds (minimal electrical stimulus to produce cardiac repolarization), which can be altered by drug interactions such as sympathomimetics that include epinephrine and ephedrine. Lower doses of sympathomimetic agents can lower thresholds by 20% to 30% compared with larger doses, which can result in elevation of pacing thresholds in conventional pacemakers. High pacing thresholds adversely reduce the battery life of the pacemaker.

Cardiac implantable devices, specifically CLS pacemakers, are used for patients with a history of third-degree atioventricular heart block not receptive to pharmacologic treatment. Pacemaker insertion in pregnant women is recommended after the eighth week of gestation. There is an option of increasing the lower rate limit of the CLS during the first trimester because of the physiologic changes such as increased cardiac output, blood volume, and reduced systemic vascular resistance that are associated with pregnancy. The current literature on managing pregnant women with cardiac disease and CLS pacemakers is limited. A European study was implemented in 2002 comparing the CLS pacemaker with conventional pacemaker function in a sample population that excluded pregnant women.

The CLEAR (Comparing Closed Loop Stimulation and Accelerator Rate-Adaptive Pacing) multicenter study compared conventional rate-adaptive pacemakers with the CLS pacemaker during episodes of mental stress, the active orthostasis test, the handgrip test, and the Valsalva maneuver. The evidence supports the premise that the CLS pacemaker’s rate-adaptive functions may be superior to those of the accelerator pacemakers. It is important, however, to note the small sample size of 60 participants. A larger European and Asian clinical prospective investigation by Lindovska et al in 2012 indicated excellent graded results and technical and medical benefits of CLS pacemakers in 80% of the 706 patients. During the clinical trials, 6.2% of patients had the CLS pacemaker mode deactivated because of intolerance to CLS. Intolerance was categorized by either shortness of breath or one of the following: high heart rate at rest, palpitations, fatigue, or discomfort. The pacemaker program was changed to either an accelerator-based rate-adaptive or nonrate-adaptive pacing mode. Alteration of the CLS pacemaker to a rate-adaptive mode was not tolerated in 2.3% of the patients. The conventional pacemaker, either single- or dual-chamber rate response, monitors the heart for a drop in rate and paces the heart at a specified programmable rate and time interval.

During pregnancy, CLS pacemakers can increase the heart rate based on their ability to sense increased metabolic demands, decreased systemic vascular resistance, and altered cardiac output by signals transmitted by the autonomic nervous system of the heart. The CLS pacemaker uses the natural adaptive cardiovascular control loop to control the heart rate and can be altered by either mental stress or hemodynamic changes (ie, cardiac output). The Figure shows a CLS rate-adaptive algorithm. Labor causes changes in endogenous catecholamines, resulting in elevated heart rate, cardiac output, and systemic vascular resistance, which can be attenuated by effective neuraxial analgesia.

In the United States, neuraxial analgesia (epidural or combined spinal-epidural analgesia) is used to provide analgesia for 60% of laboring parturients. Neuraxial analgesia is associated with reduced catecholamine levels and increased uteroplacental perfusion, which reduces cardiovascular stress. The American Heart Association released a scientific statement supporting neuraxial analgesic placement using either epidural or combined spinal-epidural narcotic technique, continuous electrocardiogram (ECG) monitoring, pulse oximetry, and continued monitoring 24 hours postpartum in pregnant patients with complex congenital heart disease. It is imperative for the CRNA to anticipate potential elevated heart rates and initiation of pacing by the CLS pacemaker in response to changes in cardiac output or mental status or in response to complications associated with intravascular injection and local toxicity. Minimizing the demands on the heart and reducing cardiovascular stress during the intrapartum period is essential to optimize maternal and fetal outcomes.

Prenaesthetic evaluation should include baseline ECG, assessment of the pacemaker device to include the function and locality of the device, current programmed settings, and date of last battery installation. The North American Society of Pacing and Electrophysiology and the British Pacing Electrophysiology Group (now British Heart Rhythm Society) developed a 5-position code system to identify the antiarrhythmic function of pacemakers (see Table). The settings noted in italics in the Table indicate the CLS pacemaker’s function and setting.

Hypotension is a common side effect of neuraxial analgesia caused by sympathetic nervous system blockade, vasodilation, and decreased cardiac preload and afterload. Preloading and coloading can reduce the incidence and effects of hypotension. Malposition of the epidural catheter can be verified by a positive test dose and aspiration of the epidural catheter. The routine use of a test dose (lidocaine or bupivacaine with epinephrine) to verify an inadvertent injection into the intravascular or subarachnoid space varies in clinical practice depending on institutional policy. The literature is limited regarding the use of a test dose in a pregnant woman with cardiac disease and a CLS pacemaker. The rate of intravascular injection ranges from 4.9% to 7% in one study and 0.6% to 2.7% in another study for subarachnoid catheterization in pregnant women compared with 2.8% in nonpregnant patients. A test dose of 1.5% lidocaine
Closed-loop stimulation (CLS) adjusts to the patient’s heart rate (HR) based on both physical and mental stress. It has the capacity to assess hemodynamic requirements by evaluating changes in right ventricle (RV) contractility triggered by the autonomic nervous system (ANS).

- The electrode tip measures and calculates changes in the RV impedance by comparing impedance curves recorded under stressful conditions with the patient’s impedance curves at rest. Closed-loop stimulation offers one of the most physiologic rate-adaptations in response to external stimulation. For instance, with external stimulation, as in the case of labor contractions and anticipation of epidural placement, there is physiologic stress and mental stress. Both these external stimulations lead to impulses carried through the ANS, and the brain orders the sinoatrial (SA) node to increase the HR due to increased cerebral metabolic demand.
- If the SA node is blocked, the stroke volume increases, thus increasing RV impedance. However, this increase in impedance is not sufficient to meet the metabolic demands.
- The CLS functions to essentially emulate the SA node by adapting the HR based on the actual metabolic demand brought about by the physiologic and mental stress.
- The following sequence of events characterizes the CLS response: SA node chronotropy sends impulses to the ANS, which then signals the myocardium isotropy; the CLS then adapts the HR, thereby increasing the cardiac output to meet the metabolic demand.
- The CLS allows for assessing real-time changes between impedance curves at rest and under physiologic and mental stress. As such, it is able to adjust pacing rates delivered by the pacemaker based on these differences. It is able to track changes in contraction so that at any time the body requires oxygen regardless of activity level, the CLS detects this and adapts by increasing the HR to meet the oxygen requirement or metabolic demand.
- Once the appropriate HR is achieved, contractility will naturally decrease, and the CLS responds by allowing the HR to reduce.

**Figure.** Algorithm of Closed-Loop Stimulation Pacemaker with epinephrine at a concentration of 1:200,000 (10-15 μg/mL) provides 80% sensitivity for verification of an inadvertent intravascular injection and is usually seen immediately after injection with an increase in heart rate and rise of 15 mm Hg or greater in systolic blood pressure. Failure to detect the malposition or placement of the epidural catheter intravascularly can result in anesthetic local toxicity, anoxic encephalopathy, and death.

The potential for cesarean delivery necessitates verification and monitoring of adequate labor analgesia for the parturient. The ability to convert a parturient’s labor epidural block to a surgical epidural anesthetic requires use of either 3% chloroprocaine or 2% lidocaine with or without epinephrine. Incremental redosing of the epidural anesthetic should be implemented cautiously, with availability of emergency resuscitative drugs and with external pacing if the pacemaker malfunctions. Electrocautery should not be used within 15 cm of the pacemaker because it generates a high-frequency electrical current and electromagnetic interference can disrupt the function of the pacemaker. Externally placing a magnet over the pulse generator activates a magnetic reed valve that closes the pulse generator and converts the pacemaker to an asynchronous mode with a fixed rate between 85 and 100/min. The CLS has a fixed-rate mode of 90/min.

This case report details the anesthetic management of a parturient with an implantable CLS pacemaker who experienced intermittent pacing after neuraxial analgesia.

**Case Summary**
At 39 weeks' gestation, a 25-year-old primigravida presented to the labor and delivery unit for induction of labor. Her history included neurally mediated syncope, third-degree heart block, and a dual-chamber pacemaker with CLS function (Biotronik Inc) implanted 7 months earlier. Her medical history included a diagnosis of multiple seizures in 2010 and admission because of multiple seizures, syncope, and high-grade atrioventricular block at 8 weeks' gestation in 2017. The CLS pacemaker was implanted following radiofrequency ablation for treatment of supraventricular tachycardia. The patient reported an episode of elevated ventricular and atrial rates 1 month following insertion of the dual-chamber CLS pacemaker. The initial cardiology note indicated that the pacemaker was paced in the atrium at 47% and the ventricle at 10% with a basic rate at 50/min. The CLS programmed response was set on high. The sensitivity for both atrial and ventricular leads was set on automatic. One month following the insertion of the CLS pacemaker, the cardiologist changed the atrial rate overdrive threshold to 170/min based on reported episodes of elevated heart rates. Remote pacemaker monitoring and device interrogation by a cardiologist continued throughout the pregnancy (and periodically following childbirth). The patient's prescribed medications included levetiracetam (1,500 mg) twice daily, a prenatal vitamin, and folic acid (1 mg).

The patient requested an epidural block at 4 cm of cervical dilation. The initial vital signs before neuraxial analgesic placement were as follows: blood pressure of 134/80 mm Hg, oxygen saturation measured by pulse oximetry.
oximetry (Spo₂) of 97%, heart rate of 114/min, temperature of 36.5°C, and respiratory rate of 19/min. A body mass index of 28 kg/m² was documented with a weight of 80 kg and height of 168 cm. Hemodynamic monitoring included continuous ECG, pulse oximetry, noninvasive blood pressure, and periodic temperature readings. A combined spinal-epidural (CSE) anesthetic technique was selected to provide rapid pain relief for the parturient. Pain scores were documented initially at 10 of 10. A CSE was placed by the Certified Registered Nurse Anesthetist (CRNA) using sterile technique, after an initial preload of 1,000 mL of Ringer’s lactate solution. The baseline heart rate before CSE placement was observed between 104/min and 110/min.

The CSE procedure was initiated at 4:22 PM. An intrathecal dose of 3 mL of 0.1% ropivacaine with fentanyl, 2 μg/mL, was given 2 minutes later; at 4:26 an epidural test dose of 3 mL of 1.5% lidocaine with epinephrine (1:200,000) yielded a negative result after 5 minutes (at 4:31). The epidural infusion of 0.1% ropivacaine with fentanyl, 2 μg/mL, was started at 4:32, with a basal rate of 12 mL/h and patient-controlled analgesia 6 mL every 20 minutes. A positive sensory block at T8 was achieved with minimal motor blockade. A reduction in numerical pain scores was noted from 10/10 to 0/10.

Ten minutes following the epidural infusion (4:42 PM), the patient had episodes of increased heart rates ranging from 160 to 170/min on the ECG at intervals of 2 to 10 seconds. The CLS pacemaker responded within seconds by reducing the heart rate to a range of 104/min and 108/min. During these increased heart rate episodes, the patient showed no symptoms of shortness of breath, chest pain, palpitations, perioral numbness, dysgeusia, or tinnitus. Minimal blood pressure changes were noted, and the episodes of elevated heart rate lasted approximately 10 minutes. The epidural catheter placement was verified a second time, with no aspiration of blood and cerebrospinal fluid.

At 5:30 PM after the parturient communicated a pain score of 8/10 with cervical dilation of 8 cm, an additional dose of fentanyl, 100 μg, and 8 mL of 0.25% bupivacaine were administered, according to institutional protocol. This resulted in a reduced pain score of 0/10. A sensory block of T8 was obtained with neither drowsiness nor sedative effects. Passive descent of the fetus allowed for minimal intervention and spontaneous delivery of a viable male infant. The Apgar scores were 8 at 1 minute and 9 at 5 minutes. A second-degree perineal laceration was repaired, with an estimated blood loss of 250 mL. The recovery was uneventful, and the patient was discharged 48 hours post partum.

**Discussion**

The elevated heart rates with intermittent pacing after the combined spinal-epidural placement was considered a nonroutine event (NRE) in a high-risk parturient. Communication with the patient in conjunction with continuous monitoring enabled the CRNA to differentiate between an inadvertent intravascular injection, impending high spinal anesthetic, or a properly functioning CLS pacemaker. A positive increase in heart rate to 160/min 10 minutes following the test dose provided some degree of suspicion regarding either migration of the catheter or potential inadvertent intravascular injection. Aspiration of the epidural catheter indicated neither cerebrospinal fluid nor blood. The patient was comfortable with minimal motor block. Failure to achieve adequate analgesia with recommended local anesthetics is associated with inadvertent catheter placement in the intravascular space.

Hemodynamically, the parturient’s elevated heart rate was the only symptom of a possible inadvertent intravascular injection. The timeline of 10 minutes was an uncommon occurrence for a positive test dose for intravascular injection. Redosing of the parturient several hours later with fentanyl and 0.25% bupivacaine resulted in pain relief with no drowsiness or sedative effects and validated correct epidural analgesic placement. The increased heart rate could be attributed to a change in systemic vascular resistance (see Figure) and cardiac output after placement of the combined spinal-epidural anesthetic, which correlates with the CLS pacemaker’s function.

The distinct advantage of the CLS pacemaker is that the built-in special sensor can immediately detect changes in the heart as a result of external stimulation (ie., CSE placement) and responds with an augmented heart rate at the earliest stage. In the case of the laboring parturient, this quick response allows for adjustments that are needed to maintain cardiac output for

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**Table.** North American Society for Pacing and Electrophysiology and British Pacing and Electrophysiology Group Generic Code for Pacemaker Settings

<table>
<thead>
<tr>
<th>Pacing</th>
<th>Sensing</th>
<th>Response</th>
<th>Rate modulation</th>
<th>Multisite pacing</th>
</tr>
</thead>
<tbody>
<tr>
<td>A = Atrium</td>
<td>A = Atrium</td>
<td>I = Inhibited</td>
<td>R = Rate modulation</td>
<td>V = Ventricle</td>
</tr>
<tr>
<td>V = Ventricle</td>
<td>V = Ventricle</td>
<td>T = Triggered</td>
<td>0 = None</td>
<td>A = Atrium</td>
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<tr>
<td>D = Dual (A &amp; V)</td>
<td>D = Dual (A &amp; V)</td>
<td>D = Dual (I &amp;/or T)</td>
<td>0 = None</td>
<td>D = Dual (A &amp; V)</td>
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<td>0 = None</td>
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*a* italics indicate characteristics of closed-loop stimulation pacemaker related to the codes for pacemakers. (Adapted with permission from Bernstein et al., 2002.)
the mother, thus protecting both the mother and the baby at various stages of labor. The ability of the CRNA to differentiate a positive test dose and an appropriately functioning CLS pacemaker reduces the risk of unnecessary catheter manipulation or replacement of a correctly placed epidural catheter.33,34

**Conclusion**

Current and emerging technology has provided women with cardiac disease the opportunity to deliver healthy babies. The increased use of CLS pacemakers among pregnant women warrants thorough preoperative consultation and evaluation by the CRNA in close collaboration with the obstetrician and cardiologist to provide analgesia for labor and/or an anesthetic for cesarean delivery. It is imperative that CRNAs have the knowledge and clinical expertise regarding pacemaker functions, rate-adaptive mechanisms, and the availability of a backup source of pacing to optimize outcomes in a population characterized by a higher incidence of morbidity and mortality.

**REFERENCES**


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DISCLOSURES
The authors have declared no financial relationships with any commercial entity related to the content of this article. The authors did not discuss off-label use within the article. Disclosure statements are available for viewing upon request.