

Spinal Cord Stimulation and the Pregnant Patient-Specific Considerations for Management: A Case Series and Review of the Literature

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Objectives: The use of spinal cord stimulation (SCS) is a form of neuromodulation used to treat chronic pain in those patients who are refractory to conventional medical management. Not uncommonly, SCS can dramatically improve a patient's quality of life, and those who are in the childbearing years may go on to become pregnant. The purpose of this case series is to describe: 1) implantation considerations in women of childbearing age; 2) use of rechargeable systems; 3) the obstetric and anesthetic concerns in patients with spinal cord stimulators; 4) risks of using SCS in the peripartum period.

Materials and Methods: Two female patients with complex regional pain syndrome I (CRPS I) who were well managed with SCS became pregnant. In both patients, the leads were placed through the T12/L1 interspace and the generator was placed in the buttock region. In the first patient, the device was deactivated prior to conception and maintained off for the duration of the pregnancy. The second patient became pregnant on two separate occasions, with active SCS for a portion of the first trimester. During her second pregnancy, the patient elected to use of SCS at 30 weeks' gestation.

Results: The developing fetuses with intrauterine exposure to SCS were followed out for a minimum of two years and are developmentally normal. The physical presence of the device did not complicate obstetric or anesthetic care. Rechargeable SCS systems were not adversely affected when turned off for the duration of the pregnancy.

Conclusion: Implantation of SCS devices in women of childbearing years should take into account the future needs of both obstetric and anesthetic care by avoiding the abdomen and lower lumbar spine *whenever possible*. There was no appreciable decline of battery capacity in present day constant current rechargeable generators when deactivated for the duration of pregnancy.

Keywords: Electromagnetic fields, obstetric and anesthetic considerations, pregnancy, rechargeable implantable pulse generators, spinal cord stimulation

Conflict of Interest: Dr. Thomas Simopoulos is a consultant for Boston Scientific and St. Jude Medical. The other authors reported no conflicts of interest.

INTRODUCTION

Over the past 40 years, there has been a rapid increase in both the technologic advancement and scope of conditions amenable to treatment by spinal cord stimulation (SCS). SCS is accepted as an earlier therapy in the chronic pain treatment continuum and is being offered to younger patients. For example, SCS has come to the forefront in the management of intractable pain related to complex regional pain syndromes (CRPS) I and II (1). SCS not uncommonly becomes the only therapy that offers clinically significant and side-effect-free pain relief. SCS therapy is particularly attractive to women of childbearing years who desire to become pregnant without the risk of possible teratogenic effects from medications (2).

However, little information exists regarding the management of these devices in patients who later become pregnant (3). Because the effects of SCS on the developing fetus are unknown, it is recommended by all manufacturers that the device be deactivated once the diagnosis of pregnancy is made. While there is one report of SCS

being used in pregnancy, there are five patients with sacral neuromodulation for lower urinary tract dysfunction who deactivated their systems at variable durations during the first trimester (2,4). The authors noted no adverse effects on the pregnancy or newborn.

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They went on to recommend that activation of the device be considered only if urinary dysfunction threatens the outcome of pregnancy.

We describe the obstetric and anesthetic management issues in two female patients with CRPS whose pain symptoms were well controlled following implantation of rechargeable SCS devices, who later became pregnant. We report the stability of rechargeable constant current implantable pulse generators (IPGs) when deactivated for purposes of pregnancy. In addition we report a case of SCS activation during pregnancy and review the literature on the potential effects of electromagnetic fields (EMF) on fertility and pregnancy.

CASE REPORTS

Case 1

The patient is a 34-year-old previously healthy woman who developed CRPS I following a left foot bunionectomy in 1999. Her symptoms were mild and were well-controlled with comprehensive medical management. She had her first child soon after developing CRPS and during the ensuing years her pain symptom intensity increased as did the demands of daily activity. By November of 2004, her pain became progressively refractory to medical management and lumbar sympathetic blocks. The patient described her symptoms as crushing left foot pain with associated tingling, burning, unpleasant cold sensations, bluish color changes, and swelling. She also reported severe pain with shaving of the left leg and slow growth of the toenails in this foot. The physical examination of the left foot was significant for edema, bluish discoloration, allodynia, and cold to touch. The bunionectomy scar was well healed and the nails were not brittle.

In February of 2005, the patient underwent a successful percutaneous trial of SCS. Several weeks later, the permanent implant was performed with dual eight contact leads placed at T9 and T10 level with the epidural spaced accessed at T12/L1. The leads were secured to the supraspinous ligament at L2, and they were tunneled to the left buttock where the implantable rechargeable pulse generator was placed (Precision, Boston Scientific Neuromodulation, Valencia, CA, USA). She subsequently reported marked pain reduction with a 75% improvement in pain intensity. By September of 2005, as a result of her improved quality of life, she became pregnant for the second time. Because of the unknown effect of SCS during pregnancy, she deactivated the device once she decided to conceive. The patient kept the SCS off, avoided medications, restricted her activities, and endured the pain for the entire pregnancy.

A healthy full-term neonate was delivered via a normal spontaneous vaginal delivery. The location of the SCS was communicated to the obstetric anesthesia team who administered lumbar epidural analgesia for the labor with excellent pain control. The rechargeable IPG was not recharged for the duration of the pregnancy and was allowed to become depleted. The generator was recharged by the patient after the delivery and paresthesia coverage was restored and no reprogramming was required. The patient is now more than four years post implant and reports no change in her recharging interval with preserved paresthesia coverage. Post partum, she used her spinal cord stimulator and reported no difficulties with lactation.

Case 2

A 39-year-old woman who was in a motor vehicle accident suffered significant trauma to her left shoulder in 1999. She required three reconstructive shoulder surgeries but suffered from adhesive cap-

sulitis and CRPS. The patient complained of cold dysesthesias through out the entire arm with associated burning pain, allodynia, skin color changes, and edema. The physical examination of the left upper extremity disclosed atrophy of the rotator cuff muscles, as well as edema and allodynia of the hand. The range of motion of the left shoulder was essentially nil.

The patient complained of progressively worsening pain on evaluation in 2002. She had tried various antidepressants, anti-inflammatories, antiepileptics, and analgesics without long-term success. A series of sympathetic and interscalene blocks did not render any significant long-term benefit. On April of 2003, she underwent a successful trial of SCS with subsequent permanent implantation. A lead with eight contacts was advanced to the level of C4 upon accessing the epidural space at T12/L1 (Genesis St. Jude Medical, Neuromodulation, Division, Plano, TX, USA). The IPG was placed in the left buttocks with an extension connecting the lead to the generator. Postoperatively the patient derived excellent pain relief with an 80% reduction in pain intensity.

As a result of her improved quality of life, she became pregnant for the first time in August of 2004. She deactivated the SCS eight weeks into the pregnancy. Her stimulator settings were amplitude of 3.30 milliamperes, a frequency of 50 Hz, and a pulse width of 400 μ sec. The left upper extremity pain returned to its baseline severe level and the patient reduced her activity and used acetaminophen with only modest benefit. She went on to deliver a healthy full-term neonate via cesarean section under general anesthesia. The anesthesiologist felt uncomfortable with regional anesthesia despite close communication on the location of the SCS. The child is now four years old and is healthy and developmentally normal on the Denver Developmental Screening Test (DDST). The DDST is a standard for measuring the attainment of developmental milestones that include fine and gross motor skills, language, and personal-social dimensions through infancy and childhood.

By April of 2005, the patient experienced ipsilateral spread of the CRPS to the left lower extremity. These symptoms did not respond to multimodal analgesics or lumbar sympathetic blocks. In August of 2006, an additional eight contact leads was placed via T12/L1 and advanced to T9/10 level. The IPG was replaced in the buttock with a rechargeable system (EON ST. Jude Medical Neuromodulation, Division, Plano, TX, USA). The device was programmed for the lower extremity with a frequency of 50 Hz, amplitude of 10.20 milliamperes, and a pulse width of 200 μ sec.

The patient became pregnant with her second child in November of 2006. She deactivated the device five weeks post conception. By 30 weeks' gestation, her pain became intolerable and through consultation with her obstetrician, the spinal cord stimulator was reactivated to cover both extremities. The patient recharged at 3-week intervals for up to 1 hour. She did not appreciate any change in the recharging interval or loss of programs having had the IPG off for approximately six months. She went on to have a cesarean delivery under epidural anesthesia. Post partum, the patient noted no disturbances in lactation. Her child is two years of age and is within normal range on the DDST.

DISCUSSION

Implantation of spinal cord stimulators in women of childbearing age requires special consideration of future obstetric and anesthetic needs. The technical considerations with regard to lead insertion as well as the IPG implantation are important to allow for smooth anesthetic and obstetric care. First, *whenever possible*, the access to

the epidural space for lead placement should be in the upper lumbar to low thoracic levels. Avoiding lower lumbar levels will facilitate neuraxial anesthetic techniques that are preferable in caring for the parturient. Second, abdominal placement of the IPG may result in both technical and biologic complications. The IPG may easily be damaged during an urgent/emergent cesarean delivery by either direct surgical trauma or EMF from the electrocautery. In the case series of sacral neuromodulation by Wiseman et al., abdominal placement of the IPG required repositioning during pregnancy because of progressive pain that was likely related to increased abdominal girth (4). In a review of cardiac pacemakers, Jaffe et al. reported ulceration of an abdominally placed IPG with advancing pregnancy (5). In both cases presented here, buttock placement of the IPG did not pose any clinical issues and the device was not damaged during the delivery of obstetric care.

Deactivation of rechargeable systems for the purpose of pregnancy did not result in any negative consequences to the function of the IPG. In case one, the IPG uses nonvolatile memory which prevents the loss of stored data and programs when all power is lost. Furthermore, even when the battery is overdischarged, the negative electrode does not dissolve and so the battery capacity remains stable (6). In the second case, the IPG was turned off when the patient still felt paresthesia. Even if there was the lowest voltage remaining (3.5 V) in the IPG, there would not be enough time in an average 40-week pregnancy to cause overdischarge and therefore decrement in IPG functional output (7). In short, present day constant current IPGs when deactivated for pregnancy are unlikely to undergo permanent capacity depletion requiring replacement because of a dissolving negative electrode.

There remains uncertainty about the impact of SCS on fertility. Our second patient and the five patients reported by Wiseman et al. all had active neuromodulation during conception without reported issues of fertility. Based on the current accepted biochemical mechanisms of SCS in pain control, none are hormonally mediated (8). Evers et al. studied the effect of repetitive transcranial magnetic stimulation (rTMS) in the treatment of affective disorders on neuroendocrine hormone levels, including cortisol, prolactin, follicle stimulating hormone, and thyroid stimulating hormone (9). They reported no change in the serum levels at the typical setting used in the treatment of depression. There are many published animal studies investigating the effects of EMF on reproduction and fetal development. Brent reviewed 58 *in vivo* and *in vitro* animal models studies evaluating the reproductive and teratogenic effects of low-frequency EMF (10). The effect on fertility was out assessed in seven of those studies. While one study showed inconsistent effects on fertility, the remaining studies all concluded no adverse effects of low-frequency (less than 3000 Hz) EMF on fertility. Anecdotally, neuromodulation may indirectly cause a relative increase in fertility by reducing pain, enhancing activity and sense of well-being thereby promoting sexual activity.

The current *recommendation* in a patient with a neuromodulatory device for chronic pain is deactivation once the diagnosis of pregnancy is made. There are no studies examining the effect of SCS on human fetal development, and it is very unlikely that any will be undertaken. Available literature consists of studies investigating the effects of electrical exposure in the parturient through accidental electrical injury, electrocardioversion for arrhythmias, and proximity of electrical devices with their associated EMF. Early case reports of 15 pregnant women receiving electrical shock between 1965 to 1992 resulted in a 73% rate of fetal demise with no maternal deaths (11–15). More recently, a prospective cohort study of 31 women

who received varying degrees of electrical shock during pregnancy demonstrated that 28 of the women gave birth to healthy newborns, one woman had a newborn with a ventricular septal defect, and the remaining two women had spontaneous abortions (16). Among their age-matched controls subjects, 30 had healthy babies and one had a spontaneous abortion. The small number of patients precludes strong conclusions; however, the increase in cardiac defect raises concerns.

On the other hand, when small voltages are applied to the mother during cardioversion, the existing literature suggests that antiarrhythmic therapy is relatively safe during pregnancy (17–19). Preclinical studies evaluating EMF effects on human fibroblast cell growth or DNA repair mechanisms fail to show adverse effects (20). No apparent reproductive effects were found in dairy cattle living in close proximity to high-voltage power lines (21). Rat embryos exposed to high-dose electric and magnetic fields (ten gauss) failed to develop toxicity at birth (22–26).

The above reported maternal exposures to EMF are likely to be greater in magnitude and with more somatic exposure than that of SCS. Implanted SCS systems generate very little electrical current and minute EMF at therapeutic range. Furthermore, while the cerebral spinal fluid is an excellent conducting medium, the surrounding vertebral bone and ligaments are highly insulating and confine this small amount of EMF to the spinal canal (27). It is very unlikely that leads in posterior epidural space in the thoracic and cervical spine generate enough EMF to penetrate the vertebral body, breach the uterine placental unit, and influence the developing fetus. The recharging of the IPG may represent more EMF than the actual SCS. The low-dose EMF produced by recharging unit transferring energy to an IPG placed in the buttock region would have to penetrate soft tissue, muscle, and iliac crest in our patients to affect the fetus. In the second case presented, given the low EMF from SCS, the fact that the fetus was in the third trimester, the lack of effective oral medications, and the unknown impact of severe chronic pain causing physical and emotional stress on pregnancy, we felt that the benefit of SCS outweighed the risks.

The diagnosis of pregnancy may be delayed for five to eight weeks post conception as reported here and previously (4). Therefore, it is reasonable to consider the potential effects of SCS on preterm labor and miscarriage. The gravid uterus is maintained in a state of quiescence through the coordinated actions of a number of unrelated hormonal and nonhormonal inhibitors, such as progesterone, prostacyclin, nitric oxide, and vasoactive intestinal peptide, among others (28). Before a pregnancy reaches term, an activation process occurs, also mediated by various hormones and peptides, involving the activation of ion channels, and an increase in myometrial gap contractions (29). As uterine quiescence and activation much like fertility are primarily regulated by circulating hormones and peptides and based on the lack of effect of rTMS on circulating reproductive hormones, it is unlikely that SCS would impact any of these factors. In animal models, Karsdon et al. demonstrated that inhibition of uterine contractility with electrical current did not correlate with changes in the levels of systemic hormones or neurotransmitters. (30). Furthermore, SCS has been well documented to cause vasodilation, and therefore is unlikely to have any adverse effects on uteroplacental blood flow (31,32). Vasodilation in preeclamptic patients with epidural anesthesia has been shown to improve uteroplacental perfusion and not cause a placental steal (33). The fact that the concern of a placental steal has not emerged as a true phenomenon during the sympathectomy from epidural anesthesia and analgesia makes it less likely

that the modest modulation of the sympathetic nervous system by SCS would be adverse.

There remain no formal data on the effect of SCS on fetal heart rate (FHR) monitoring. In the second case reported, the patient did not have to turn off her SCS during FHR monitoring because of interference. Internal electronic FHR monitoring utilizes a wire electrode penetrating the fetal scalp with a second lead attached to the mother, usually on the inner thigh. The very low current emitted during SCS is unlikely to influence the FHR monitor. More commonly, external electronic FHR is employed and a Doppler ultrasound detects fetal heart valve movement and pulsatile blood ejection systole to generate an FHR tracing (34). As the implanted SCS has no moving parts, the device would have no effect on this method of FHR monitoring.

Early discussion between the treating physician and the anesthesiologist is critical for facilitation of anesthetic care. The SCS therapy should not be expected to provide reliable analgesia for labor pain or cesarean delivery. As mentioned above, the leads responsible for SCS when placed in a rostral fashion at the thoraco-lumbar junction of the spine will not be damaged when labor epidurals and spinals are used. A caudal approach is no longer routinely used in obstetric anesthesia practice for several reasons including a lack of dependability for analgesia during the first stage of labor, inadequate anesthesia for unexpected emergent cesarean section, and a high complication rate that includes pelvic visceral injury and injection into the fetus (35). Intrathecally placed medications will not impact the function of SCS in any way, as reported by centers that implant SCS devices under spinal anesthesia. Epidurally placed leads for SCS are not likely to migrate when epidural solutions are injected. These leads cause fibrous deposits in the epidural space that form an encapsulating sheath (36). Furthermore, they are secured to the supraspinous ligament with silastic anchors and nonabsorbable sutures. In the cases reported here, both epidural anesthesia and analgesia proceeded without incident and paresthesia coverage was preserved.

Even with rostral lead placement, there does remain the risk of a neuraxial infection of the hardware when regional anesthesia is used. The development of an epidural abscess after instrumentation of the neuraxis in the obstetric population and spinal cord stimulator patients is a rare event (37,38). We would expect this complication to be very uncommon, but nonetheless vigilance should be maintained. Given the low number of patients with SCS implants who become pregnant and undergo regional anesthesia, it is unlikely that an estimated risk of infection will be known in the near future.

During the postpartum, both of the patients used SCS for analgesia in order to meet the demands of the newborn. The patients reported no ill-effects on milk let down. Based on rTMS data, lactation is unlikely to occur without difficulty. SCS may benefit the neonate by reducing exposure to analgesics and adjuvants (e.g. antidepressants and antiepileptics) through breast milk.

CONCLUSION

Implantation of spinal cord stimulator devices in women of child-bearing years requires careful consideration for future obstetric and anesthetic care. The deactivation of present day rechargeable technology for the purposes of pregnancy does not seem to cause deterioration of the generator. While accumulating preclinical and clinical data suggest that low-frequency EMF does not adversely affect fertility and pregnancy, the possible teratogenic and aborto-

facient effects of neuromodulation cannot be excluded. Therefore, the *current recommendation* is to deactivate SCS devices during pregnancy. Reactivation during pregnancy should only be considered with a careful risk vs. benefit analysis. The impact of uncontrolled chronic pain on a developing fetus and the abortive potential has not been adequately evaluated. Utilization of SCS is likely to be beneficial in the postpartum period to facilitate maternal care of the neonate as well as reduce drug exposure from the breast milk.

Authorship Statement

Dr. Bernardini conducted background literature review on the topic of EMF and pregnancy. He collected the case series and provided the initial draft. Dr. Pratt provided intellectual input regarding obstetrical anesthesia concerns in a patient with SCS. Dr. Takoudes provided expertise from the obstetrical view on SCS use during pregnancy and lactation. Dr. Simopoulos prepared the final draft for submission. He incorporated his experience and concerns when implanting patients who became pregnant and had an implanted rechargeable SCS. All authors reviewed and approved the final manuscript.

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COMMENTS

This is a well written and thorough case report and review written by authors who clearly have experience in chronic pain management, spinal cord stimulation and obstetric anaesthesia.

Any medical intervention during pregnancy will be viewed with concern until there is sufficient experience. We know that SCS has a profound effect on abnormal physiological processes which have been altered by the disease process. (For example the abolition of allodynia with SCS in neuropathic pain or the improvement in tissue oxygenation in ischaemic pain). However SCS produces very little neurophysiological change in normal subjects. Despite this it is right to have concerns in the normal pregnant state as well.

We really should be advocating a registry of SCS in pregnancy so that we can in the future better inform our patients and their medical attendants of the use of SCS during pregnancy. Until then we have to rely on sporadic case reports such as these.

The authors of this article make suggestions both on future implant technique in women of child bearing age and on how to manage the implant once pregnancy is diagnosed.

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Chronic pain and pregnancy always represent a management challenge. Neuropathic pain in particular can be very difficult to treat because of the unknown long term effects on the developing fetus of our standard medications. Bernardini et al (1) present two case studies that outline many of the considerations and challenges that face implanters treating women who are considering pregnancy. These principals are also a consideration for all premenopausal women. As is pointed out in the article, long term effects on pregnancy and the baby are not answered by these two case reports. The perspective of needing to manage pain is vital when considering risk and benefit decisions.

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The paper by Simopoulos, Bernardini, Pratt, and Takouides adds valuable information to the literature regarding the patient who becomes pregnant. The management of these women is often confusing, and to both the patient and physician can be a stressful endeavor. This article shares the experience with two patients to give the reader some insight into issues that may arise and the management of those issues.

Perhaps of equal importance is the review of the current literature which is very helpful in the process of the informed consent for patients of childbearing age.

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