Case Report

Spinal Cord Stimulation for Complex Regional Pain Syndrome: A Case Study of a Pregnant Female

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Background: Spinal cord stimulation (SCS) is a form of neuromodulation, used to treat chronic neuropathic pain refractory to conventional medical management. Spinal cord stimulators are treatment options when intractable chronic pain has not responded to more conventional treatment modalities. Currently, the use of SCS is contraindicated in pregnancy. Nevertheless, many SCS/neuromodulation recipients are women of child bearing age who may become pregnant. There are no published reports that focus on the possible side effects of SCS or neuromodulation therapy on human fertility, fetal development, pregnancy, delivery, or lactation.

Objectives: The purpose of this current report is to present a case study on the use of SCS/neuromodulation during pregnancy.

Study Design: Presentation of the case of a 24 year old female who became pregnant after receiving an SCS implantation for pain control secondary to complex regional pain syndrome (CRPS). The SCS was in use at the time of conception but deactivated when patient became aware of her pregnancy and intermittently reactivated for five minute intervals throughout the entire pregnancy.

Results: Currently very little documented evidence is available regarding the safety of using a SCS/neuromodulator during pregnancy; therefore its use during pregnancy is contraindicated. Available literature suggests that, women who have chosen to keep the SCS/neuromodulator activated during pregnancy have delivered healthy babies without any life threatening complications.

Limitations: Case presentations do not provide conclusive evidence of treatment effectiveness. This data is only preliminary and future studies should be used to assess outcomes and measures to provide quantification of the SCS implantation during pregnancy.

Conclusions: Women of child bearing age who are recipients of SCS/neuromodulation implantation should be informed of the limited knowledge available regarding the impact of SCS/neuromodulation use during pregnancy. For current recipients, decisions about ongoing use during pregnancy should be an individual decision based on the potential risks and benefits.

Key words: Pregnancy and complex regional pain syndrome, pregnancy and reflex sympathetic dystrophy, pregnancy and spinal cord stimulators, pregnancy and electromagnetic fields, and pregnancy and neuromodulator.

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Spinal cord stimulation (SCS) is a form of neuromodulation therapy used to treat chronic pain syndromes such as failed back surgery syndrome (FBSS), chronic arachnoiditis, diabetic neuropathy, ischemic limb pain, phantom limb pain, refractory unilateral limb pain, angina, acute herpes zoster pain, post-herpetic neuralgia, and complex regional pain syndrome (CRPS), which is the focus of

this paper (1-9). Spinal cord stimulators are treatment options when intractable chronic pain has not responded to more conventional treatment modalities (10,11). Neuromodulation therapy is an established treatment modality because it improves quality of life by reducing pain (12). It is currently being offered to younger patients because of its predominately side-effect-free pain relief (12). The effects of SCS/neuromodulation on the fetus are an important consideration because of the possibility of teratogenic and abortofacient effects. There are no published reports that focus on the possible effects of SCS or neuromodulation therapy on fetal development, pregnancy, delivery, or lactation (1,14). Long-term effects of SCS on child development have yet to be studied, although a few case studies have been reported.

The purpose of this article is to present a case report of a woman with an implantable spinal cord stimulatro who became pregnant. Potential complications of SCS/neuromodulation use during pregnancy will be reviewed followed by a discussion about SCS/neuromodulation effects on fetal development and lactation.

Case Report

Medical History

The following case study illustrates the use of a spinal cord stimulator in a 24-year-old woman who developed CRPS following a work-related injury of the right hand. After the injury, she developed pain, edema, temperature and color changes, and hyperhidrosis of both her upper extremities. Two years after the initial injury, after she exhausted numerous conventional therapies, she was referred to our interventional pain management center to be evaluated for a spinal cord stimulator. Initially she was not interested in SCS therapy but eventually agreed to do a SCS trial. Prior to the trial she rated her pain to be 9 of 10 using a visual analogue scale (VAS) (0 = no pain; 10 = worst pain). During the trial, the pain decreased to 4 of 10 and many of her other symptoms subsided. She reported 99% coverage and greater than 50% relief of pain in her upper extremities. Given the successful results of the trial, she received a SCS implant shortly thereafter. The Boston Scientific epidural paddle electrode was placed at C3-C5 and the implantable pulse generator was positioned in the left buttock area. The SCS was so successful she was able to have her fentanyl patch decreased from 100 mcg/3 day period to 37 mcg/3 day period. When the stimulator was activated she rated her upper extremity pain a 3 – 5 of 10 and when it was deactivated her pain increased to 8 – 9 of 10. Hence, she found it necessary to have the spinal cord stimulator on approximately 18 hours a day.

SCS and Pregnancy

A month after the SCS implant, she informed the interventional pain management center she was 4 weeks pregnant and requested advice regarding use of the spinal cord stimulator during her pregnancy. After consulting the manufacturer, it was recommended to the patient that she deactivate the device during the pregnancy due to limited data availability on safety and efficacy throughout the pregnancy. She informed the clinic staff that she was unable to keep the spinal cord stimulator deactivated during the first trimester because her Lyrica® and fentanyl had been discontinued by her obstetrician causing the pain to be too severe and she found it necessary to turn the spinal cord stimulator on for short intervals intermittently. Sometimes, however, she was able to forego activation for a day or 2. During a 12 week SCS implant follow-up phone call to the patient, she informed staff she was not using any pharmaceutical analgesia or the spinal cord stimulator. Surprisingly, her pain level had diminished to a 1 – 2 of 10 except for one episode where she experienced vaginal pressure that necessitated consultation with her obstetrician. An ultrasound of the fetus showed it to be developing within normal limits. The symptoms quickly resolved and she reported no further difficulties except for occasional intermittent pain that necessitated intermittent use of the spinal cord stimulator for short periods of time. At a follow-up SCS appointment during her eighth month of pregnancy she reported a pain level of 1 – 2 of 10 with occasional increases where she would turn on the spinal cord stimulator "for five minutes." She stated she thought the periods of less pain were attributed to increased hormone levels as a result of her pregnancy. However, very little research is available documenting whether the hormones produced during pregnancy decrease pain levels in patients diagnosed with neuropathic pain disorders such as CRPS.

Follow-up

This individual delivered a full-term baby boy via vaginal delivery without complications. However, a month post-partum her CRPS symptoms began to return and by 7 weeks post-partum the pain intensity was severe enough to cause her to reactivate her spinal cord stimulator for 16 hours/day to keep her pain level no

greater than 3 of 10. The patient was able to care for her child who she stated has developed normally and at 4 months weighed 16 pounds. The patient underwent another pregnancy under similar circumstances 3 years following her first child. The spinal cord stimulator was used continuously from conception through 50% of the pregnancy. The patient again noticed her CRPS symptoms resolving throughout the pregnancy. The patient delivered a full-term healthy infant without complication. After delivery, the patient has experienced a return in her CRPS symptoms.

Discussion

Several points for discussion are illustrated here. First, very little empirical data is available documenting the safety of spinal cord stimulator use during pregnancy (Table 1). Overwhelmingly, though, spinal cord stimulator manufacturers and most health care professionals do not currently advocate the use of SCS/neuromodulation therapy during pregnancy. In fact, even the manufacturers of these units do not advocate their use during conception or pregnancy because of the lack of empirical data. In this case, SCS therapy was active during conception and used episodically throughout pregnancy without visible harm to either the mother or the baby.

Technical Complications

SCS/neuromodulator lead placement and implantable pulse generator placement are concerns that may arise during pregnancy (1,6,15). The woman discussed in the case study by Saxena and Eljamel (6) required surgical cutting of the lead extender at 28 weeks gestation as a result of pain that developed at the juncture of the epidural lead and lead extender. The implantable pulse generator was located in the abdomen. The pain and the surgical cutting may have been avoided had the implantable pulse generator been placed in the buttock area instead.

Lead migration, lead perforation and, although very rare, infection are concerns when spinal anesthesia is used for delivery in a patient with a spinal cord stimulator/neuromodulator (16,17). Conversely, Bernardini et al (1) explained that epidural leads "cause fibrous deposits in the epidural space that form an encapsulation sheath" so the leads are not apt to migrate from injection of epidural medications as some health care providers are concerned about (1,18). Furthermore, medications given intrathecally, as in spinal anesthesia, have no effect on a spinal cord stimulator's/neuromodulator's function or lead placement (1). As long as the lead extender is placed far enough from the midline, lead perforation when inserting an epidural needle can be avoided (19). Likewise, as long as strict sterile technique is utilized when placing the epidural catheter for spinal anesthesia, infection is very rare and prophylactic antibiotics are not warranted (19).

Spinal Cord Stimulator/Neuromodulator and Fetal Development

The use of a spinal cord stimulatoror any neuromodulation therapy during pregnancy is debatable. As mentioned previously, very little is known about the safety of SCS/neuromodulation therapy during pregnancy. Reviews and meta-analysis of the effects of SCS on conception, pregnancy, and labor have not been conducted, obviously, due to ethical issues (8,9,20). Therefore the safety and efficacy of SCS use during conception, pregnancy, and labor have not been established. Nor have the potential developmental effects that might emerge later in childhood or for that matter even later in life (2). Consequently, use of a SCS/neuromodulation unit has been contraindicated during pregnancy or even for those considering pregnancy by both physicians and spinal cord stimulator/neuromodulator manufacturers (1-2,6-7,9,13-15,21). However, some women choose to ignore the contraindications, become pregnant, and continue to utilize spinal cord stimulators/neuromodulators during pregnancy. Some physicians believe if a pain control method must be used during pregnancy, the use of the spinal cord stimulator/neuromodulator is a better option than pharmaceutical agents because many medications prescribed to control pain and other symptoms of neuropathic pain have known teratogenic effects (2,13-14).

Spinal cord stimulators/neuromodulators emit a very weak electromagnetic field (EMF) that may cause concern for a developing fetus (13). However, Bernardini and colleagues (1) claim very little electric current and very small amounts of EMF are generated from a spinal cord stimulator/neuromodulator. Ito et al (13) explained the magnetic permeability of body tissue and the distance from the spine to the uterus allow very little, if any, EMF to come in contact with the "pelvic visceral area." Another issue to consider is the impact that severe chronic pain and the hormonal and biochemical effects of stress and depression, along with the risk of self-neglect or inadequate prenatal care may have on a developing fetus (1-2). Therefore the benefit of SCS/neuromodulation may outweigh the

Table 1. *Key characteristics and outcomes of pregnancies in women receiving spinal cord stimulator (scs) therapy for pain management.*

Study Author	Pregnancy Number	SCS Status	Course of Pregnancy	Outcome of Pregnancy	L & D Management	Alternative Pain Management	Technical Complications
Bernardini, et al (2010)	1 34 y/o	Turned off prior to conception	Normal	Healthy full term baby	Vaginal delivery, epidural, no complications	None	None. Implantable pulse generator (IPG) depleted during pregnancy and recharged after delivery with no problems
Bernardini, et al (2010)	1 39 y/o	Turned off @ 8 wks & off duration of pregnancy	Normal	Healthy full term baby	Cesarean section (C/S) under general anesthesia. No complications	Acetaminophen with moderate benefit	None
	2: 40 y/o pt had a 2nd SCS implanted after 1st pregnancy	Both turned off @ 5 weeks, back on @ 30 weeks	Normal	Healthy full term baby	C/S with epidural anesthesia-no complications	Turned SCS back on at 30 weeks	None
Federoff, et al (2012)	1 34 y/o	Turned off @ 8 wks	Normal	Healthy full term baby	Emergent C/S under spinal anesthesia-failure to progress	Oxycodone 5mg/ acetaminophen 325mg 6X/day; Gabapentin 300mg TID	Reported decrease efficacy prior to pregnancy & could not get IPG to work properly. "uncomfortable stimulation in abdomen"
	2 35 y/o	Turned off @ 8 wks when learned of pregnancy	Labor @ 33 wks, otherwise normal	Healthy preterm baby @ 33 wks	Elective C/S with spinal anesthesia	Oxycodone 5mg/ acetaminophen 325 mg 6X/day; gabapentin 300 mg TID	Unable to reactivate IPG after 2nd pregnancy due to decreased efficacy
Hanson & Goodman (2006)	1 37 y/o	On throughout pregnancy	Normal	Healthy full term baby	Vaginal delivery with epidural anesthetic	None	_
	2 38 y/o	On throughout pregnancy	Normal	Healthy full term baby	Vaginal delivery with lumbar epidural anesthetic	None – SCS on during entire pregnancy	_
Ito et al (2012)	1 40 y/o	On throughout pregnancy	Became pregnant via artificial insemination	Healthy full term baby	Elective C/S with spinal anesthesia	_	_
Saxena & Eljamel (2009)	1 30 y/o	On during pregnancy until 28th wk, then lead surgically cut	Developed pain at juncture of epidural lead (EL) and lead extender (LE) surgically cut at 28 wks	Healthy full term baby	_	SCS on until 28th wk	LE cut at 28 wks due to pain probably caused by increasing abdominal girth
Segal (1999)	1 31 y/o	On throughout pregnancy	Delivered at 35 wks; otherwise	Healthy preterm baby @ 35 wks	Not discussed	SCS	_
Summerfield et al (2010)	1 35 y/o	On throughout pregnancy; Off during C/S	Delivered early @ 32 wks due to IUGR	Healthy preterm baby @ 32 wks	C/S under spinal anesthesia. SCS off for delivery	Bisoprolol 10 mg daily; Morphine 40 mg daily; Diazepam 15 mg daily; Tramadol 400 mg daily; Also smoked 1 ppd	_

Table 1 (cont). *Key characteristics and outcomes of pregnancies in women receiving spinal cord stimulator (scs) therapy for pain management.*

Study Author	Pregnancy Number	SCS Status	Course of Pregnancy	Outcome of Pregnancy	L & D Management	Alternative Pain Management	Technical Complications
Takeshi-ma et al (2010)	1 28 y/o	On intermittent-ly during entire pregnancy	Normal	Healthy full term baby	Vaginal delivery; no complications	SCS intermittently	None
	2 29 y/o	On intermittent-ly during entire pregnancy	Normal	Healthy full term baby	Vaginal delivery; no complications	SCS intermittently	None
	3 34 y/o	On intermittent-ly during entire pregnancy	Normal	Healthy full term baby	Vaginal delivery; no complications	SCS intermittently	SCS became ineffective after birth; epidural lead wire broken in 2 places; replaced and worked well
Wise-man et al (2002)	1 (1st pregnancy 29 y/o	Off 2 wks prior to conception; turned back on 1 wk after delivery	No complications	Healthy pre-term baby @ 38 wks 2 days	Vaginal delivery; no complications	No meds; turned on 1 week prior to delivery	Device turned on 7 days before birth but deactivated 6 days later due to "uncomfort-able stimulation"; Still had off 8 months after delivery
	1 (2nd pregnancy) 37 y/o	On at concep-tion; off at 8 wks when learned of pregnancy	No complications	Healthy full term baby	Vaginal delivery; no complications	None	After delivery still had to self-straight catheterize though still had good results with post-void residual; not happy with pain relief so had neuromodulator removed
	1 (2nd pregnancy) 30 y/o	On at concep-tion; off at 7 wks when learned of pregnancy	No complications	Healthy pre-term baby @ 34 wks	Vaginal delivery; no complications	None	IPG repositioned at 15 wks due to pain at IPG site
	1 (1st pregnancy) 27 y/o	On at conception; turned off at 8 wks when learned of pregnancy	No complications	Healthy; pre-term elective C/S @ 38 wks	Elective C/S "to prevent lead damage" to neuromodulator	None	Turned back on 4 days after delivery & functioned well; became ineffective @ 11 wks post-partum; lead revision planned
	1(1st pregnancy) 26 y/o	On at concep-tion; turned off when learned of pregnancy	No complications	Healthy full term baby; elective C/S	Elective C/S no complications	_	Not reactivated after delivery; able to void and completely empty bladder
	1 (2nd pregnancy)	On at conception; turned off at 9 wks when learned of pregnancy; on at 19 wks due to difficulty self-catheterizing	No complications	Healthy full term baby; elective C/S	Elective C/S no complications	_	No problems when reacti-vated after delivery
Yoo et al (2010)	1 32 y/o	On during "first few" wks of preg-nancy; turned off when learned of pregnancy	Spontaneous abortion @ 6 wks	Spontaneous abortion @ 6 wks	_	Propranolol 20 mg daily; Mirtazapine 30 mg daily; Trama-dol 50 mg BID; Buspirone 15 mg daily; Solifenacin succinate 5 mg daily, Mefenamic acid 250 mg daily; Ethyl loflazepate 1 mg daily; Sodium tianeptine 12.5 mg daily	_

Table 1 (cont). *Key characteristics and outcomes of pregnancies in women receiving spinal cord stimulator (scs) therapy for pain management.*

Study Author	Pregnancy Number	SCS Status	Course of Pregnancy	Outcome of Pregnancy	L & D Management	Alternative Pain Management	Technical Complications
This author's case study	1 (2nd pregnancy) 24 y/o	On @ conception; off t 4 wks when learned of pregnancy; reactivate intermittently 'for 5 minutes' during the 2nd & 3rd trimester	Normal	Healthy full term baby	Vaginal delivery with epidural anesthesia	Turned IPG on intermittently "for 5 minutes" during 2nd & 3rd trimester	None

Note. SCS = spinal cord stimulator; IPG = implantable pulse generator; C/S = cesarean section; IUGR = intra-uterine growth restriction; wks = weeks; ppd = pack per day.
Adapted from Fedoroff et al. Spinal Cord Stimulation in Pregnancy; A Literature Review. *Neuromodulation* 2012: 15:539.

risks. Federoff and associates (2) suggested if a woman decided to continue the use of SCS/neuromodulation therapy during pregnancy, she must be under careful regular medical supervision throughout the course of the pregnancy.

Spinal Cord Stimulator/Neuromodulator and Lactation

In the reviewed case studies, only 2 studies addressed potential effects of SCS/neuromodulation on lactation. Bernardini et al (1) reported that use of a spinal cord stimulator in the postpartum period did not cause any concern with "milk let down" in the 2 women discussed in their case study. In fact, the authors surmised the use of SCS/neuromodulation for post-partum analgesia probably was more beneficial to the newborn because the neonates did not receive analgesics or other medications such as antidepressants and antiepileptics through the breast milk. Federoff et al (2) also reported no difficulties with lactation by their patient during her 2 pregnancies.

Conclusion

SCS/neuromodulation therapy is a cost effective treatment for many chronic neurogenic pain syndromes. Currently very little documented evidence is available regarding the safety of using a spinal cord stimulator/neuromodulator during pregnancy; therefore its use during pregnancy is contraindicated. However, the available literature suggests that women who have chosen to keep the spinal cord stimulator/neuromodulator activated during pregnancy have delivered healthy babies without any life-threatening complications. Therefore, keeping a spinal cord stimulator/neuromodulator activated during pregnancy, for pain control, might be a viable option. However, if this option is chosen, close monitoring and a multidisciplinary approach including obstetrics, neonatology, pain medicine, and anesthesia is important to assure a good outcome.

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