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Pregnancy in Woman with Spinal Cord Stimulator for Complex Regional Pain Syndrome: A Case Report and Review of the Literature

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Spinal cord stimulation (SCS) is used to manage chronic pain syndromes and it is accepted a cost-effective therapy. Child-bearing women who had SCS become or choose to become pregnant despite these policies pregnancy is a relative contraindication. A 32-year-old woman had SCS as a treatment for the CRPS I of the left lower extremity. During various check up tests, we happen to find out that her serum beta-hCG was positive and confirmed pregnancy. SCS is not recommended in pregnancy because the effects of SCS on pregnancy and nursing mothers had not been confirmed. However, many female patients suffering from chronic pain may expect future pregnancy and we think that they must be informed about the possibility of pregnancy and the effects of SCS device implantation in the course of pregnancy. First of all, a good outcome requires a multidisciplinary team approach, including obstetrics, neonatology, pain medicine and anesthesia, as was used from an early pregnancy. Unfortunately, she had a misabortrion after 6 weeks. (Korean J Pain 2010; 23: 266-269)

Key Words:
labor, pregnancy, spinal cord stimulation.

Spinal cord stimulation (SCS) is becoming an increasingly popular method for the treatment of chronic pain syndromes, including diabetic neuropathy, failed back surgery syndrome, complex regional pain syndrome, chronic arachnoiditis, phantom limb pain, ischemic limb pain, refractory unilateral limb pain syndrome, angina, postherpetic neuralgia and acute herpes zoster pain. The goal of the treatment is not a cure, but a therapeutic option that can significantly reduce pain and improve the quality of life for most patients. In addition, SCS has been proved to reduce the typical medication dose needed [1,2]. It is now widely used for a number of indications (over 14,000 SCS implantations occur annually world-wide [3]). Given the annual SCS implantation growth rate, SCS is likely to be

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used more frequently in parturient care. We report a rare case of pregnancy in a woman with a spinal cord stimulator and review the literature on pregnancy in women with SCS.

CASE REPORT

A 32-year-old woman with SCS presented for consultation in court regarding documentation concerning her injuries related to a traffic accident she had experienced. She had received SCS implantation at another hospital several months earlier as treatment for CRPS I of the left lower extremity. Her chronic pain syndrome stemmed from the unfortunate complications of a previous pedestrian traffic accident in which she was struck on the backside by a car. Lumbar spine X-rays and MRI were within normal limits, but she suffered from allodynia, hyperalgesia, motor weakness and temperature fluctuations at that time. Despite extensive physical therapy, anxiolytic therapy, several local anesthetic blocks, four sympathetic blocks, transcutaneous electric stimulation and adjunctive pharmacological management, her condition failed to improve. During the early period of SCS implantation, her pain was reduced to an acceptable level, but when she presented for consultation at our hospital, she clearly required pain relief. The electrodes entered the L3-4 interspace, and the end of the electrode was located in the epidural space at the T9-10. The generator was then implanted in the anterior abdominal wall. At the time of her visit to our pain clinic, she was receiving propranolol HCl 20 mg, mirtazapine 30 mg and tramadol HCl 50 mg twice a day, along with buspirone HCl 15 mg, solifenacin succinate 5 mg, mefenamic acid 250 mg, ethyl loflazepate 1 mg and sodium tianeptine 12.5 mg daily. During various checkup tests, we found that her urine beta-hCG was positive, which is the case in women of childbearing age. Thus, her serum beta-hCG was checked, revealing that it was 150.19 mIU/ml. Immediately, we consulted the obstetric department, and eventually pregnancy was diagnosed, but ultrasonographic visualization did not rule out the possibility of ectopic pregnancy, a tubal abortion state or, less likely, early pregnancy. She was informed about this and further tests were recommended. However, she quit her therapy at our hospital and transferred to a hospital closer to her home for the management required. Upon her discharge, we informed her that there were no animal or human studies regarding possible teratogenic effects or fetal/maternal risk of using SCS at the time of conception, pregnancy, or labor. We also explained that despite all the risks, pregnancy is possible if she desired and recommended that a good outcome requires a multidisciplinary team approach, including obstetrics, neonatology, pain medicine and anesthesia, as was used in an early pregnancy. Unfortunately, she had a missed abortion after 6 weeks.

DISCUSSION

Management of patients with chronic pain syndromes during pregnancy can be challenging, particularly in the presence of SCS. SCS is an accepted cost-effective therapy for many chronic pain syndromes. The safety and effects of SCS during pregnancy have not been established, and pregnancy is a relative contraindication according to the FDA and the manufacturers of the related devices [4]. Various meta-analysis and reviews of the effects of SCS have not included this group of patients [2,5,6]. However, SCS is increasingly used to manage chronic pain in a female in her reproductive years may present. Child-bearing women who had SCS become or choose to become pregnant despite these policies.

Reviewing the literature in English, we found four case reports of SCS in pregnancy. In the first case, a 31-year-old woman with cervical SCS of CRPS II allowed potentially teratogenic painkillers to be discontinued before conception. The cervical SCS electrode end was in the epidural space at the C2-3 interspace, and the generator was implanted in the upper gluteal region instead of the abdomen owing to the patient's concern of discomfort during pregnancy and the risk of damage if a caesarean section was necessary. This patient had a full-term safe vaginal delivery despite the SCS being turned off the time of labor and delivery. The disadvantages of using teratogenic analgesics were overcome by SCS [7]. In the second case, a 37-year-old woman with cervical SCS of CRPS I presented for epidural analgesia for labor. She was taking no medication. The electrodes entered the C7-T1 interspace and the ends of electrodes were located in epidural space at the C3 level. The generator was implanted in the left lower buttock. The spinal cord stimulator continued to function well throughout the entire process. A year and a half later, particularly interesting, the same patient presented again to their labor and delivery unit for another

delivery. She again received lumbar epidural analgesia [8]. The third case involved a 31-year-old woman with the cervical SCS of CRPS II. She developed severe pain at the side of her abdomen at the junction between the electrode and the lead extender. This is different from the previously reported cases in that the generator was implanted in the anterior abdominal wall. The electrode end was placed at the T6 level. She developed new severe pain at the side of the abdomen at the junction between the epidural lead and the lead extender. Therefore, the lead extender was surgically cut with the generator switched off during the 28th week of gestation under local anesthesia. She went on to deliver a normal healthy baby at full term [9]. The last case, a 35-year-old woman with lumbar SCS for lumbosacral pain was admitted for an urgent caesarean section. She had a Mallampati score of III and poor dentition with loose teeth. The electrodes were inserted at L2-3 and located at T8 and the generator was implanted in the left upper buttock. A caesarean delivery was planned, and spinal anesthesia was therefore performed below the SCS leads at the L4-5 level. A healthy infant was delivered [10].

In our case, the patient received a lumbar SCS implantation with CRPS I. She experienced a missed abortion 6 weeks after the procedure. There were no significant changes in the symptoms of CRPS or in the pattern of pain during pregnancy or after the abortion. We suspected three different possible causes for the abortion. First, her medications for chronic pain at that time may have been the cause [11]. The patient was receiving propranolol, mirtazapine, tramadol, solifenacin succinate, mefenamic acid (category C; excretion into breast milk unknown), buspirone HCl (category B; is not excreted in breast milk), ethyl loflazepate, and sodium tianeptine (not available). For category C drugs, it is known that "animal studies show some fetal risk but or no animal/controlled studies have been done." Hence, there is a considerable possibility that these drugs may have been the cause of the abortion [12]. Secondly, a literature search on the use of SCS in humans during pregnancy retrieved only one study [13]. Significantly elevated human placental lactogen and estriol serum levels were found as having a correlation to the onset of therapy at a specific week of gestation. This, however, is rarely the cause of birth defects or miscarriages. Thirdly, the possibility of natural abortion must be taken into account. The overall miscarriage rate is reported as 15-20%, which implies that 15-20% of recognized pregnancies result in miscarriage [14].

The number of cases of SCS implantation continues to grow, and it is important to realize that there is always the chance to encounter a pregnant patient. The possibility of missed abortion, as mentioned previously, and other considerable facts related to pregnancy and delivery must be realized and kept in mind.

Concerning the implantation of SCS, special attention must be paid for child-bearing woman. The generator is implanted posterior in the flank area away from the belt line or in the buttock area to avoid abdomen pain. If the patient complains of severe pain at the junction between the electrode and the lead extender, simple division of the electrode distal to the junction will resolve the problem. There is little guidance available regarding the perioperative anesthetic management of patients with SCS, but experience with deep brain stimulators, which use a similar technology, may be relevant [15-17]. Artifacts on electrocardiography have been noted during SCS, deep brain stimulation and transcutaneous nerve stimulation [18]. The current location of the electrode, lead extender and generator is ascertained by previous radiographs to assess the need for any special measures if neuraxial anesthesia is indicated. However, the location of the electrodes can change significantly. Thus, real-time ultrasound examinations may be useful. Potential risks include damage to the electrodes due to the spinal or epidural needle, introducer or catheter. If neuraxial anesthesia is performed, a meticulous sterile technique is essential. Although regional techniques are currently widely accepted, if possible general anesthesia is considered to be a better method in patients with SCS. Surgical diathermy or electrocautery can damage the lead insulation, cause temporary suppression of the neurostimulator output, and lead to reprogramming of the neurostimulator [8,15]. Monopolar diathermy should be avoided when possible in the presence of SCS, as painful electrical shocks have been reported; such shocks have not been described with generator turned off or when bipolar diathermy is used. Bipolar diathermy appears to be safe if all components are distant from the implanted equipment [16].

Above all, a good outcome requires a multidisciplinary team approach, including obstetrics, neonatology, pain medicine and anesthesia, as was used in an earlier pregnancy in our case. This will allow sufficient time to proceed to the next steps before any potentially urgent situation.

We believe that there must be a guideline concerning the treatment of chronic pain in patients expecting a future pregnancy. These patients must be informed that SCS device implantation can replace the disadvantages of using teratogenic analgesics. In addition, postpartum follow-up, with special emphasis on the SCS function, must be documented. Informed consent should be obtained regarding the possibility of disrupting the function of the SCS and due to infection risk. Postoperatively, the clinical efficacy of SCS should be checked by the neurostimulator as any device or programming issues can be identified in this manner. Most importantly, cautious follow up visits to the obstetric department throughout the pregnancy are absolutely necessary.

In conclusion, SCS is not recommended in pregnancy because the effects of SCS on pregnancy and nursing mothers have not been studied. However, many female patients suffering from chronic pain may expect future pregnancy, and we think that they must be informed about the possibility of pregnancy and the effects of the SCS device implantation during the course of their pregnancy. We also hope that this report will elicit the interest of physicians to report other cases involving the conception, pregnancy, and labor management of patients with spinal cord stimulators in order to confirm the safety of this modality under these circumstances.

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