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Dural Puncture During Spinal Cord Stimulator Lead Insertion: Analysis of Practice Patterns

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Abstract

Background: Spinal cord stimulation (SCS) is an important modality for intractable pain not amenable to less conservative measures. During percutaneous SCS lead insertion, a critical step is safe access to the epidural space, which can be complicated by a dural puncture.
Objectives: In this review, we present and analyze the practices patterns in the event of a dural puncture during a SCS trial or implantation.
Methods: We conducted a survey of the practice patterns regarding spinal cord stimulation therapy. The survey was administered to members of the Spine Intervention Society and American Society of Regional Anesthesia specifically inquiring decision making in case of inadvertent dural puncture during spinal cord stimulator lead insertion.
Results: A maximum of 193 responded to a question regarding dural punctures while performing a SCS trial and 180 responded to a question regarding dural punctures while performing a SCS implantation. If performing a SCS trial and a dural puncture occurs, a majority of physicians chose to continue the procedure at a different level (56.99%), followed by abandoning the procedure (27.98%), continuing at the same level (10.36%), or choosing another option (4.66%). Similarly, if performing a permanent implantation and a dural puncture occurs, most physicians chose to continue the procedure at a different level (61.67%), followed by abandoning the procedure (21.67%), continuing at the same level (10.56%), or choosing another option (6.11%).
Conclusions: Whereas the goals of the procedure would support abandoning the trial but continuing with the permanent in case of inadvertent dural puncture, we found that decision choices were minimally influenced by whether the dural puncture occurred during the trial or the permanent implant. The majority chose to continue with the procedure at a different level while close to a quarter chose to abandon the procedure. This article sets a time stamp in practice patterns from March 20, 2020 to June 26, 2020. These results are based on contemporary SCS practices as demonstrated by this cohort, rendering the options of abandoning or continuing after dural puncture as reasonable methods. Though more data is needed to provide a consensus, providers can now see how others manage dural punctures during SCS procedures.

Keywords: Spinal Cord Stimulation, Neuromodulation, Dural Puncture, Chronic Pain, Patient Safety, Postdural Puncture Headache

1. Background

Spinal cord stimulation (SCS) is an important treatment modality for chronic intractable neuropathic pain. It is beneficial for a variety of chronic pain conditions, including failed back surgery syndrome, CRPS, or other causes of neuropathic pain (1-7). SCS is considered to be safe with low incidence of serious long-term adverse events (8-

11). The process of spinal cord stimulation begins with percutaneously inserting cylindrical leads into the dorsal epidural space during a trial period. If the patient reports satisfactory relief, a permanent system can be implanted. Two methods for permanent implantation are used: cylindrical leads via a percutaneous needle, or paddle leads that are inserted via open laminectomy.

Whereas SCS is considered safe it is not without complications; studies show complications rates as high as 30 to 40% (10, 12, 13). Both hardware-related problems and biological complications can arise, with hardware-related problems being more common (10, 13). Hardware complications include lead fracture or disconnect, lead migration or malposition, battery failure, or unexpected device trouble (5, 8, 9). Biological complications include infection, pain related to the device, allergic reaction, seroma, dural puncture, and nerve or cord injury (8-10, 13, 14). For both SCS trials and permanent implantations, a critical step is safe access to the epidural space, which can be complicated by a dural puncture.

Accidental dural puncture during SCS procedure occurs when the needle punctures the dura mater while accessing the epidural space, but can also be caused by the SCS lead itself with studies showing frequencies ranging from 0.2 to 3% (13, 15). A recent retrospective review reported the rate of dural puncture with SCS procedures at 0.81%, with all the patients subsequently having a postdural puncture headache (PDPH) (16). Dural puncture management has received little attention compared to the other, hardware-related problems, possibly due to its low incidence due to use of fluoroscopy (10, 17, 18). However, it is the most common neurological complication of SCS (12). It is important to review the risk factors for dural puncture and the clinical features and course of subsequent PDPH which is the most likely consequence.

Studies have shown that patients with the following risk factors are at high risk of experiencing a dural puncture during SCS: female sex, 31 - 50 years of age, previous history of PDPH, previous surgery at the needle entry, obesity, spinal stenosis, scoliosis, calcified ligamentum flavum, and patient movement (12, 19, 20). Procedural techniques that increase the risk of dural puncture are midline approach, angle of entry greater than 60°, perpendicular bevel orientation during the procedure, and use of the retrograde approach (12). The contralateral oblique view has been shown to provide greater consistency in epidural localization; it is superior to the lateral view and may further help reduce the risk of inadvertent dural puncture (21, 22). PDPH is diagnosed intraoperatively via the presence of cerebral spinal fluid (CSF) during epidural access and/or lead placement/positioning. Postoperatively patients may present with signs and symptoms consistent with PDPH or a hygroma at the lead-anchoring wound site.

PDPH is defined by the International Headache Society as a "headache that occurs within 5 days of a lumbar puncture". It is usually associated with neck stiffness and/or subjective auditory symptoms, has spontaneous resolution within 14 days, or responds to an autologous blood patch" (23). Believed to be caused by a slow CSF leak through the ruptured meninges leading to intracranial hypotension and reactive vasodilation, PDPHs are described as bilateral occipitofrontal, dull or throbbing in character, and positional (worse in the upright position) (18). Along with PDPH, patients experiencing a significant dural puncture may have intracranial hypotension, which can lead to tinnitus, cervicalgia, diplopia, photophobia, nystagmus, nausea, and subdural hematoma (10, 12, 24, 25). Other rare but significant complications include cerebral venous thrombosis, bacterial meningitis, convulsions, cerebral infarction, cranial nerve palsies, persistent headache, and persistent low back pain (13, 26).

Postdural puncture headaches are a self-limiting condition for a majority of patients; resolving within a week with conservative measures (12, 16). However, during SCS procedures a large bore needle (eg, 14 gauge) is used to access the epidural space for lead positioning, which increases the risk of PDPH with dural puncture (16, 20, 27, 28).

Clinicians can approach dural punctures during SCS in multiple different ways, and no uniformly accepted practice currently exists. The Neuromodulation Appropriateness Consensus Committee (NACC) of the International Neuromodulation Society (INS) has recommended several practice modifications that will lead to improved care during SCS trials and implantations; however, no specific guidelines were provided regarding dural puncture management (10). The NACC has encouraged implanting physicians to better disseminate lessons learned from studies and registries, develop guidelines based on best available evidence and expert consensus, and periodically reassess such practice guidelines and their effects (10). We believe it is important to know the practice parameters of peers to verify one's own clinical approach in addition to implementing possible modifications and improvements from this knowledge.

2. Obectives

We administered a survey assessing multiple technical aspects of SCS practice and here we present and analyze the practice patterns in case of inadvertent dural puncture during the SCS procedure. We strive to understand how other clinicians manage dural punctures during both the trial phase as well as the permanent implant in hopes to

clarify what is acceptable standard of care and to provide some guidance for the management of this complication.

3. Methods

We created a survey with 31 questions related to various aspects of spinal cord stimulation practice. It was submitted and approved by the Institutional Review Board and, subsequently, approved by the Boards of American Society of Regional Anesthesia (ASRA) and Spine Intervention Society (SIS). An email invite request was sent to recipients (active membership of these societies) requesting their anonymous participation in the survey by clicking on a Survey Monkey Link. The survey was sent to 2967 members of SIS with 1259 opening the email and 3169 members of ASRA with 1477 opening the email. The total resulted in 6136 emails sent and 2736 emails opened. Of those that opened the emails, a maximum of 195 responses were received. A calculated response rate was based on the number of recipients who actually opened the email as "true recipients". Additionally, since these are multispecialty societies, and SCS is a specialized procedure that is restricted to a selected cohort, we estimate that between 10 and 20 percent of the recipients were truly eligible for this survey. However, this remains an estimate based upon the diversity of pain practitioners and especially since ASRA is also devoted to regional anesthesiology. The total number of unique "true recipients" is even less given the overlap in the membership between the two societies. We did not make any adjustment for this since the true number of overlapping members is unknown. In this review, we present the findings covering common practices by interventional pain physicians in the event of a dural puncture while performing a SCS trial or a SCS implantation. The two questions related to this were:

(1) If a dural puncture occurs during SCS trial, I would _____.

(2) If a dural puncture occurs during a SCS permanent implantation, I would _____.

4. Results

Survey responses were received between March 20, 2020 to June 26, 2020, with 193 participants responding to question 1 regarding dural punctures while performing a SCS trial and 180 participants responding to question 2 regarding dural punctures while performing a SCS implantation. The response rate for question 1 and 2 among respondents who opened the email and assuming 10% eligibility versus 20% eligibility to participate in the survey is presented in Table 1.

A maximum of 193 responded to question 1 and 180 responded to question 2. The proportion and confidence interval for the percentage and total number that responded to the questions are presented in Table 2.

If performing a SCS trial and a dural puncture occurs, a majority of physicians chose to continue the procedure at a different level (56.99%), followed by abandoning the procedure (27.98%), continuing at the same level (10.36%), or choosing another option (4.66%). Similarly, if performing a SCS implantation and a dural puncture occurs, a majority of physicians chose to continue the procedure at a different level (61.67%), followed by abandoning the procedure (21.67%), continuing at the same level (10.56%), or choosing another option (6.11%).

5. Discussion

The survey shows that most interventionalists will continue their procedure at a different level when faced with an intraoperative dural puncture during either SCS trial or permanent implantation (56.99% and 61.67%, respectively). However, other intraoperative approaches were also represented, including abandoning the procedure, continuing the procedure at the same level, or utilizing various other methods, revealing a wide variability of practice patterns. We will discuss the advantages and disadvantages of different management approaches to intraoperative dural punctures during SCS trials and during permanent implantation to create a decision-making tool that may be of value to interventional pain physicians.

When a dural puncture occurs, the patient may develop a PDPH due to a CSF leak. The headache does not present intraoperatively, and CSF leakage may or may not be evident during the procedure. Practitioners typically must wait and monitor the patient for these complications in the immediate postoperative period (few hours to days). The specifics of each procedure can help a pain physician decide which of the previously mentioned choices are ideal for their practice.

5.1. Percutaneous SCS Trial

A percutaneous SCS trial is the first intervention in SCS. The physician will place temporary leads percutaneously and attach them to an external battery for the patient to "trial" the device. Physicians look for improved function, pain relief, and sleep in their SCS trial patients. If a dural puncture occurs and the patient is experiencing a significant amount of pain from a PDPH that cannot be effectively treated, assessing the success of the SCS trial can be difficult (29). Given this rationale, it would be best to delay/abort a SCS trial after dural puncture due to risk of a failed trial from a PDPH.

Table 1. Estimated Response Rates to Questions Regarding the Management of an Accidental Dural Puncture During Placement of a Percutaneous Spinal Cord Stimulator

Question #	Email Sent	Email Opened	Respondents	Skipped	Calc RR [a] (10%)	Calc RR [b] (20%)
1. DP on trial lead placement	6136	2736	193	3	70.5%	35.3%
2. DP on permanent lead placement	6136	2736	180	16	65.8%	32.9%

Abbreviations: DP, dural puncture; Calc RR, calculated response rate.
[a] Based upon assumption that 10% of true recipients were eligible for this survey. We did not adjust for the overlap leading to a lesser total number of recipients.
[b] Based upon assumption that 20% of true recipients were eligible for this survey. We did not adjust for the overlap leading to a lesser total number of recipients.

Table 2. Immediate Approaches to the Management of an Accidental Dural Puncture During Placement of a Percutaneous Spinal Cord Stimulator Lead(s) for Trial and Permanent Procedures

Question	Abandon the Procedure		Continue at Same Level		Continue at Different Level		Other	
	No. (%)	(95% CI)	No. (%)	(95% CI)	No. (%)	(95% CI)	No. (%)	(95% CI)
1. DP during trial	54 (27.98)	(21.66 - 34.26)	20 (10.36)	(6.06 - 14.66)	110 (56.99)	(49.99 - 63.99)	9 (4.66)	(1.66 - 7.66)
2. DP during permanent	39 (21.67)	(15.67 - 27.67)	19 (10.56)	(6.06 - 15.06)	111 (61.67)	(54.57 - 68.77)	11 (6.11)	(2.61 - 9.61)

Abbreviations: DP, dural puncture; CI, confidence interval.

However, it is often more convenient for the patient and the physician to proceed rather than abort the procedure despite acknowledging the suboptimal conditions that may arise from the dural puncture. In addition, some insurance companies may not approve a repeat trial. Scheduling a repeat trial may also be difficult or inconvenient, both for the patient as well as the physician. Alternatively, the patient may not develop a PDPH or not develop a headache severe enough to impact the quality of the SCS trial. Given this information, physicians may choose to proceed with the procedure at a different level or at the same level. Proceeding at a different level (in which a dural puncture did not occur) reduces the risk of placing intrathecal leads.

Considering all the above, most physicians in our survey chose to continue the trial at a different level reflecting a possible preference to convenience and hoping for no significant headache complaints to affect the quality of the SCS trial or early positive trial results before the onset of a headache. One must keep in mind that the incidence of PDPH after large bore needle puncture is very high. Early positive results, before the headache occurs, can be challenging with some subthreshold programming that often have a delayed wash in period. Additionally, with new modes of SCS programing options becoming available, there may be a longer trial period when traditional programming is failing and alternative programs are evaluated (15, 19, 29). Another viable option may be to continue the trial and perform a prophylactic blood patch. We did not assess this specifically within our survey; however, this may be reflected in the answer choice "other". When making clinical decisions within one's own practice, one can use the collective patterns in this cohort as well as the outlined advantages and disadvantages of each approach to help choose what seems to be best serve each patient's interest. Our data suggests that there is no minimal standard of care, and that best practice may include either trial continuation at a different level or aborting the procedure completely. While continuing the trial at a different level is acceptable, caution may be advised when considering continuing the trial at the same level as the dural puncture considering the increased risk (intrathecal lead placement) of this approach. Additionally, only 10.36% of the cohort would proceed at the same level, making this a less acceptable practice.

NACC guidelines do not provide specific guidance on the best practice approach following dural puncture. Considering the goals of the trial, the best approach may be to abandon the procedure. However, based upon the survey data of peers, proceeding with the procedure is practiced by most physicians and appears to be acceptable practice. A prophylactic low volume targeted blood patch may be reasonable if choosing to proceed with the trial as there is a high likelihood of PDPH with large bore needles, and this approach may salvage the trial if PDPH is prevented. Low volume and extreme caution would especially be needed if performing blood patch at upper thoracic level or cervicothoracic junction. A rationale for continuing or aborting SCS trials in case of dural puncture is presented in Table 3.

5.2. Percutaneous Permanent SCS Lead Insertion

A percutaneous permanent SCS lead insertion is performed after a successful SCS trial, in which the patient experienced > 50% pain relief and improved sleep and function. Two approaches are commonly used for this procedure: (1) the physician accesses the epidural space percutaneously via a needle and places the leads prior to making the incisions for anchoring and battery implantation, and

Table 3. Rationale for Continuing or Aborting a Spinal Cord Stimulator Trial If a Dural Puncture Occurs

	Continuing	Aborting
Percutaneous trial	(1) Patient convenience; (2) Physician convenience; (3) Headache may not occur; (4) Trial may be short and patient notices benefit in pain and function before headache; (5) A prophylactic blood patch may prevent PDPH, but this is not assured.	(1) Trial may be inadequate because of headache; (2) Can do adequate trial another time; (3) Can do epidural blood patch without worrying about leads or infection

(2) the physician makes the incision first before accessing the epidural space and lead placement.

The goal of the procedure is to implant the leads since a successful trial was already performed. With this logic, it would be best to proceed after dural puncture, when performing permanent SCS implantation since the outcome should be consistent with the trial if the implant is successful. However, the option of aborting the procedure was also presented if dural puncture occurred during permanent lead insertion. It is predictable that PDPH occurs after large bore needle insertion and most patients will need a blood patch (16, 20, 23). Motivating factors to abort the procedure may include concern for likelihood of performing a blood patch, increased risk of infection, complicated post-operative course, and risk of neural injury.

The majority of respondents in our study continued with the implant but accessed the epidural space at a different level. However, almost a quarter of respondents chose to abort the implant procedure. In deciding what to do in one's own practice, one can take heed from the practices of their peers and assess the risks/benefits of each option on a case-by-case basis. Both continuing and aborting after dural puncture during permanent implantation seem to be practiced by a significant number in the cohort. The potential advantages and disadvantages of each approach are presented in Table 4. We did not clarify whether practitioners aborting the implant had already made an incision. Though we believe that physicians who abort the procedure during implant, more likely than not, do not begin with an incision or cutdown technique. Lastly, continuing at the same level was practiced by only a few (10.56%) and given the risks of entering the thecal space, this practice would seem to be an outlier based upon the practices of this cohort. It may be more likely that this cohort of physicians begin with an incision targeting a specific vertebral level, thereby committing them to a more restricted procedural approach. In the NACC guidelines the evidence for continuing with the procedure at the same level, changing to a different level, or to abandon the procedure was classified as III (descriptive studies only), and recommendation level as C (neither recommendable nor in-advisable) and best left to the clinical judgement of the treating physician (15).

Based upon the goals of the implant procedure, the best approach would be continuing with the procedure, especially when the incision has already been made, and this approach is practiced by the majority. Abandoning the procedure is also acceptable based upon the results of the survey especially if there is anticipated post-operative complications, possible increased risk of infection, or if there is any possibility of neural injury. A prophylactic blood patch would make less sense since PDPH would not affect the overall outcome as it would during the trial.

5.3. Epidural Blood Patch and Other Approaches During SCS Procedures

The NACC discusses intraoperative blood patch and assigns evidence level III and recommendation C - neither recommendable nor inadvisable to this approach (15). Studies have shown that a prophylactic (intraoperative) epidural blood patch (EBP) can be effective in treating PDPH (30-33). Other studies have shown that it may not be efficacious in prophylaxis of PDPH (34). A small percentage of the responding physicians reported that they would use a different approach than the three provided (4.66% pursue this approach during SCS trials with dural punctures; 6.11% during SCS implantations). While this question was not further clarified by these recipients, other possible management decisions may include performing an epidural blood patch intraoperatively, after a known dural puncture, or postoperatively prior to onset of PDPH symptoms (prophylactically). Since this question was not directly asked, it is not clear how many physicians would perform a prophylactic blood patch. It is possible that physicians who do not abort after a dural puncture perform a prophylactic blood patch. The advantages and disadvantages of a prophylactic epidural blood patch for each stage of SCS are listed in Table 5.

For treating the subsequent PDPH, NACC recommends conservative measures, such as bedrest, caffeine, and IV fluids (10, 12, 15). For PDPHs that are refractory to conservative measures, the NACC proposed performing an epidural blood patch (EBP) (15). Numerous studies have shown that epidural blood patches effectively can treat PDPHs throughout many fields, especially obstetric anesthesiology.

When performing an epidural blood patch, the provider must be aware of the amount of blood being

Table 4. Rationale for Continuing or Aborting a SCS Permanent Implantation If a Dural Puncture Occurs

	Continuing	Aborting
Permanent with leads first without incision	(1) Patient convenience; (2) Physician convenience; (3) Headache may not occur; (4) Can do blood patch	(1) Avoid complicated postoperative course with seroma/headache; (2) Can do blood patch without worrying about increased infection risk; (3) Any possibility of neural injury
Permanent with leads after incision	(1) Patient Convenience; (2) Physician Convenience; (3) Headache may not occur; (4) Can do blood patch; (5) Avoid second surgery	(1) Avoid complicated postoperative course with seroma/headache; (2) Can do blood patch without worrying about increased infection risk; (3) Any possibility of neural injury

Table 5. Rationale for Prophylactic Epidural Blood Patch If a Dural Puncture Occurs During SCS Procedure

	Advantages	Disadvantages
Prophylactic EBP (trial)	(1) If successful can have a good trial after dural puncture; Avoid therapeutic patch which is very often needed	(1) Might not work and lead to an unsuccessful trial; (2) Might not be needed
Prophylactic EBP (permanent)	(2) If successful will not need therapeutic blood patch; Smooth postop course, avoid seroma, headache;	(1) May not work; (2) May not be needed and could be an unnecessary procedure with additional risk of infection during post-operative procedure that could have been avoided; (3) May be difficult to obtain blood in a draped patient

injected at the level of the dural puncture, because small volumes of blood are required at thoracic and cervical levels (35). The NACC also warns that EBPs can be a source of infection (15). The use of an EBP in the setting of an implanted SCS device introduces the risk of deep infection with the implanted hardware (15, 16). During the trial phase, the leads severe as a conduit for microorganisms to infect the deposited epidural blood. However, EBP even in the presence of hardware with careful aseptic technique has been shown to be safe and efficacious (16). Thus, the interventionalist must weigh the risk of an untreated headache against potential hardware infection.

Other measures and regional nerve blocks have been shown to provide pain relief for patients suffering from PDPH but do not always eliminate the need for EBP (36-38). The standard treatment for refractory PDPH remains an EBP as it has been shown to be highly effective with relatively minimal complications in the hands of a trained interventionalist (24, 25, 39). In addition, new epidural fibrin sealant or glue have been shown to be an effective replacement for blood, which can be a nidus for infection (40). If the patient continues to experience pain that is refractory to the EBP, more invasive options are available, which include surgical exploration and surgical closure of the dural perforation (29, 30).

5.4. Study Limitations

This article presents the practice parameters of 193 practitioners for management of dural puncture during SCS trials and 180 practitioners for management of dural puncture during SCS permanent implants. We attained this cohort through surveying general membership of a Spine Intervention Society and American Society of Regional Anesthesia. Limitations include the inability to send this survey through a dedicated Neuromodulation Society because of logistic restrictions. A second limitation is that the true response rate is not known. Since these are not primarily neuromodulation societies with variable membership from different disciplines, we estimate that only 10 - 20% of the recipients who opened the email were eligible for this survey as we calculated in the results. However, we did not adjust for any overlap in the membership leading to a possible lower number of total recipients since the magnitude of overlap was not known. Ultimately for these reasons the true response rate remains unknown.

Response rate is important as there is potential for bias when only a certain category of participants may respond and skew the results. This is however a descriptive survey looking for objective practice patterns. The individuals more likely to respond to the survey are those more interested and involved in the field of neuromodulation. These responders are unlikely to skew the results and furthermore adds value to those looking for practice patterns of their peers. This survey provides pilot data, though larger surveys in the future may help further solidify the trends seen in this survey.

5.5. Conclusions

This survey gives pilot data about SCS practices around inadvertent dural punctures from a large cohort of practicing physicians. Whereas the goals of the procedure would support abandoning the trial but continuing with permanent implant in case of inadvertent dural puncture, we found that decision choices were minimally influenced by whether the dural puncture occurred during the trial or

permanent procedure. The majority chose to continue with the procedure at a different level while close to a quarter chose to abandon. These results are based on contemporary practices as demonstrated by this cohort, rendering the options of abandoning or continuing the procedure as reasonable methods. Question of prophylactic blood patch was not specifically asked, but a low volume targeted patch may make sense when proceeding with a trial after inadvertent dural puncture to meet the goals of the procedure. Though more data is needed to provide a consensus, providers can now see how others manage dural punctures during SCS procedures and how this management will evolve.

Footnotes

Authors' Contribution: Study concept and design: WAS, JH, IU, TTS, MMA, LK, JG; Analysis and interpretation of data: JH, IU, OV, TTS, MMA; Drafting of the manuscript: WAS, JH, IU, OV, TTS, FI, HK, MMA, LK, JG; Critical revision of the manuscript for important intellectual content: WAS, JH, IU, OV, TTS, FI, HK, MMA, LK, JG; Statistical analysis: WAS, JH, MMA, LK, JG.

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Data Reproducibility: The data presented in this study are openly available in one of the repositories or will be available on request from the corresponding author by this journal representative at any time during submission or after publication. Otherwise, all consequences of possible withdrawal or future retraction will be with the corresponding author.

Ethical Approval: This has been a survey study.

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