A New Technique of “Midline Anchoring” in Spinal Cord Stimulation Dramatically Reduces Lead Migration

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ABSTRACT
Spinal cord stimulation (SCS) is a popular method of treatment of chronic pain. Unfortunately, migration of the lead continues to be a serious complication of this therapy. In an attempt to reduce lateral migration of the SCS lead, we performed a retrospective assessment of a new technique of percutaneous lead placement. This new method of “midline anchoring” of the lead using the plica mediana dorsalis was tested against conventional technique in a retrospective study involving 122 trials and 91 implants of SCS over a period of five years. The use of “midline anchoring” resulted in a decrease in lead migration from 23% to 6% after trial insertion and from 24% to 7% after implantation. We conclude that “midline anchoring” of the SCS lead is an effective method of preventing lead migration.

KEY WORDS: lead migration, spinal cord stimulation.

INTRODUCTION
Spinal cord stimulation (SCS) is progressively growing in popularity as a modality of treatment of certain chronic pain conditions. Its efficacy and safety have been firmly established by multiple studies (1–4). The applications for this therapy are getting wider and now include not only diseases of the spine and peripheral nervous system, but also a variety of other entities, such as interstitial cystitis (5), peripheral vascular disease (6), and coronary artery disease (7). Numerous technical improvements in SCS systems and better understanding of appropriate applications of this treatment have allowed significant enhancement in the results of therapy (4). Nevertheless, there are some problems and complications that still plague SCS, despite different approaches used to amend them. One of the biggest problems remains migration of the lead.

Lead migration, with loss of proper pain coverage, still plagues percutaneous SCS implantation. The rates of SCS revision are in the 14–24% range, which translates into significant additional cost, not to mention increased patient dissatisfaction (1,2).

We schematically divide migration of the lead into two categories: vertical and lateral. With real three-dimensional instead of schematic two-dimensional
visualization of the structure of the epidural space, the “lateral” migrations also include some ventral (or dorsal, which is highly unlikely) movement of the lead. In some cases, it is so extreme that the lead ends up in the anterior epidural space, causing more distress to the patient rather than pain relief. With the new anchors, such as the plastic twist-lock anchor and the beaded or “bumpy” anchor (Medtronic, Inc., Minneapolis, MN), movement of the lead in a vertical direction is mostly eliminated. On the other hand, with conventional placement of the lead there is nothing (except possible scar tissue) that prevents lateral shift. Even worse is the situation where the lead is positioned in the “physiologic” midline to provide bilateral stimulation. Any lateral movement can produce complete loss of stimulation on one side.

In an attempt to reduce lateral migration of the SCS lead, we introduced a new technique of percutaneous lead placement that we called “midline anchoring”. This retrospective study is dedicated to assess the efficacy of “midline anchoring” of the lead in the prevention of SCS lead migration.

MATERIALS AND METHODS

General Methodology

Results in 78 consecutive patients who underwent SCS trial using the “midline anchoring” technique of percutaneous lead placement were compared with a group of 44 patients, who had “conventional” percutaneous lead placement during the trial. The same comparison was performed between 62 consecutive patients after implantation of SCS with “midline anchoring” of the lead and 29 patients after “conventional” SCS implantation. All evaluations of the results were done retrospectively.

Patients were almost equally divided by gender (53% male and 47% female) and had an average age of 51 (range, 25 to 81). One of every five patients had bilateral pain. Description of the nature of pain is presented in Table 1.

All patients had a 4–5 day trial of SCS with the lead anchored only at the skin with a single silk suture. Implantation of SCS was considered only after a patient report of 60% or better relief of pain. In the vast majority of cases, the plastic twist-lock anchor was used to anchor the lead to the supraspinous ligament. All patients were treated in our clinic from October 1997 to October 2002. Follow-up interval after implantation ranged from six months to five years and was on the average 2.8 years.

Technique of “Midline Anchoring”

The four-electrode percutaneous lead (Pisces Quad, Medtronic, Inc.) was inserted contralaterally to the side of the pain and advanced to the anticipated level of stimulation (Fig.1A). The stylet was removed and manually bent slightly more, then reinserted with the tip facing the midline (Fig.1B). The lead was advanced through the midline, where a mild resistance was usually experienced (Fig. 1C). The lead was then rotated with the tip again facing toward the midline and moved slightly further in the cephalad direction (Fig. 1D).

The stylet was then removed and the lead pulled back slightly. This last maneuver practically always brought the tip somewhat closer to the midline (Fig. 1E).

The following are examples of lead position adjustments that were routinely made to optimize coverage. In cases of unilateral pain, the lead was left with electrode #3 at the midline (Fig. 2A),

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Conventional trial</th>
<th>Midline technique trial</th>
<th>Conventional implant</th>
<th>Midline technique implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failed back surgery syndrome</td>
<td>28</td>
<td>41</td>
<td>20</td>
<td>37</td>
</tr>
<tr>
<td>Spinal stenosis</td>
<td>4</td>
<td>7</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>CRPS</td>
<td>5</td>
<td>13</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Peripheral poly neuropathy</td>
<td>2</td>
<td>8</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Mononeuropathy</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
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<td>1</td>
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while in patients with bilateral pain, the midline electrode was #2 (Fig. 2B). At this point, stimulation was initiated and different combinations of electrodes were used. If necessary, additional adjustments in position were made by either slightly pulling the lead down or (more infrequently) advancing it further. In a certain number of cases, where some difficulties were encountered in advancing the lead on the contralateral side, slight adjustments were made to the technique described above. The lead was inserted on the ipsilateral side, positioned across the midline, and then pulled back with electrode #1 at the midline (Fig. 2C).

**Conventional Technique**

The conventional technique of percutaneous SCS lead placement usually involves ipsilateral placement of the lead to the side of pain without crossing the midline or straight midline placement of the lead for bilateral or axial pain.

Immediately after surgery, patients in both groups reported stimulation coverage of at least 90% of their pain area.

**Data Analysis**

Two-sided Fisher's Exact tests were conducted to compare the rate of migration experienced with the two implant techniques. All statistical analyses were performed using SAS (version 8.2, SAS Institute, Inc, Cary, NC). *P*-values < 0.05 were considered statistically significant.

**RESULTS**

Forty-four patients underwent SCS trial lead placement using the conventional technique. In this group, 23% (10) of the patients experienced migration of the SCS lead.

In six cases, reprogramming of the electrode sequence restored coverage of the pain area, while
in the other four appropriate stimulation was not restored.

Seventy-eight patients had SCS trial performed with the “midline anchoring” technique. In this group 6% (5) of the patients had migration of the SCS lead. In three cases, adequate stimulation was restored by reprogramming the electrode sequence; in the other two, loss of pain coverage was irreversible.

Twenty-nine patients underwent SCS implantation with conventional positioning of the lead. In this group, 24% (7) of the patients required revision of the SCS due to migration of the lead. Two patients had their lead replaced; three had a laminotomy lead (Resumo, Medtronic, Inc.) replacing the percutaneous lead; two patients had an additional lead placed to cover lost axial or bilateral stimulation. Finally, two more patients, who did not experience lead migration, required an additional lead placement for new onset or worsening of their pain, contralateral to the stimulation area.

Sixty-two patients had SCS implantation performed using the “midline anchoring” technique. In this group, 6% (4) of the patients required revision due to migration of the lead. One patient had percutaneous lead replacement; one had a laminotomy lead to replace the percutaneous lead; two patients had an additional lead placed to cover lost axial or bilateral stimulation. Additionally, one patient had a second lead placed for new onset of pain, contralateral to the stimulation area.

The rate of migration experienced using the midline technique was statistically significantly reduced compared to the conventional technique, both during trial and after implant ($p < 0.05$) (Table 2).

Of all the patients who experienced migration of the lead after implantation, only two reported it later than four months after surgery. The average time from initial surgery to first signs of lead migration was 37 days.

### DISCUSSION

Spinal cord stimulation is one of many widely used modalities in the treatment of failed back surgery syndrome, as well as an array of other different diseases (3,4,8). It is a safe and reversible procedure that has also been proven to be cost effective (2).

Unfortunately, one significant problem associated with SCS implantation, migration of the lead, is still not resolved. The rate of migration is varied in the literature from 13% to 69% (9–12). A review article by Turner et al. showed an average migration occurrence to be around 24% (1). Revision or replacement of the lead costs $2700–$5450 (2), which leads to an increase in the cost of the procedure by approximately 15–20%. Repetitive surgery, as well as time spent without adequate coverage, will doubtless decrease patient satisfaction with SCS.

There is no serious and detailed discussion in the literature of the lead migration problem during the trial period. Nevertheless, based on an informal poll, it is fairly high (2nd annual National Forum of Independent Pain Clinicians meeting, Chicago, 2001, personal communication). According to one of the retrospective studies, 75% of the patients called during the trial period with complaints of inadequate coverage, which, in significant part, was due to lead migration (13).

Despite a serious effort to resolve this problem, contemporary medicine cannot find an effective method that will completely prevent lead migration. Laminotomy implant will improve stability of the lead. On the other hand, not only will it noticeably increase the magnitude of the procedure and its cost, but it will also make it less easily reversible.

The other trend has been to use two leads, placed in the epidural space parallel to each other, on each side of the midline (9,13). This, of course, will increase the chance of migration, since each of the leads can move, and will allow a higher chance of recapturing desirable stimulation due to the multiple electrode combinations available (9,13). The drawback of such an approach is increased cost of the procedure, due to the use of an extra lead and dual channel generator, and an increase in the length of the procedure. The other possible problem is less effective coverage than with a single lead, especially for axial pain (14).
Besides, even with dual leads, the rate of migration requiring revision is 8–11% (9,15).

Multiple new anchors developed in the last few years have practically eliminated vertical migration of the lead, but have not done anything for horizontal stability. Our clinic has developed a new approach to positioning of the SCS lead based on stabilizing it using the plica mediana dorsalis (16). Luyendijk first described the plica mediana dorsalis duerae matris in 1963 as a median fold of the dural membrane at the dorsal side, separating the epidural space into two lateral compartments (17). Since that time, its existence has been confirmed intraoperatively, during postmortem studies, and with endoscopy and computed tomography (18–20). Besides a dural fold, “dorsomedian ligamentous strands” (21) were observed in all studies. They present themselves, in some cases, as strands of connective tissue, sometimes as a complete membrane, and sometimes, even as a triangular space filled with a fat tissue. The presence of connective tissue narrows the midline space, contrary to the popular belief that the epidural space is widest in the dorsal midline (18).

There are a few researchers who do not believe in the presence of a midline membrane (22,23), implying that all they could find is a “fat pad” (23). Nevertheless, even they do not doubt that this structure can serve as a “barrier” for a liquid injected in the epidural space.

The important issue for our method is only that there is some band/membrane in the dorsomedian epidural space, narrowing it and separating epidural compartments. This structure can serve as an additional point of “fixation” to enhance horizontal stability of the lead. The direction of forces acting on the lead should prevent lateral movement of the tip. A detailed technique of implantation is described in the Materials and Methods part of this article.

Our study showed the ability of “midline anchoring” to significantly reduce the rate of lead migration and consequently the rate of lead revision and replacement. This resulted not only in more patient satisfaction due to reduced migration rate, but also in significant cost savings. The latter was partially achieved by using a single lead system for bilateral pain in a majority of the cases.

One of the drawbacks of this new lead positioning method is that not all patients have a well-enough developed plica mediana dorsalis to allow successful use of the “midline anchoring” technique. This is well documented by our current knowledge of epidural space anatomy (17,20). As soon as free movement of the lead across the midline is recognized, a change in the initial plan is in order. The “midline anchoring” technique is applicable only for lumbar and thoracic placement of the SCS lead and cannot be used for cervical or sacral positions.

CONCLUSION

Use of the plica mediana dorsalis to stabilize the SCS lead resulted in a dramatic reduction in the frequency of lead migration and subsequent surgical revision. The “midline anchoring” technique produces increased horizontal lead stability with a decreased incidence of lead migration.

REFERENCES


