Length of SCS Trial and Type of Lead

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Disclosure
I make my living providing medical services to patients

Industry: Consulting, speaking, research

Leadership
NANS
ASIPP
Sin City vs West Virginia

Neurostimulation Therapy
What are the goals of therapy?

- Functional improvement, ADL’s
- Pain control, reduction of oral medications
- Reduction of side effects
- Return to work

Ultimately:

*Quality of life*

What is the goal of trialing?

*To increase the odds that the goals of therapy are met*
Why Trial?

• Before the patient and physician make the decision to proceed with a permanent implant, they have the opportunity to test efficacy directly and specifically.¹

• Trial stimulation may reduce the rate of failed permanent implants and improve cost effectiveness ²

• Required by payors


Why Trial?

• Demonstrate adequate paresthesia coverage

• Opportunity to judge current requirements and base choice of (IPG)

• Gives the patient an opportunity to understand and adapt to the variability of paresthesia sensations eg with postural changes
SUCCESSFUL TRIAL

- Stimulation covers area of pain
- Stimulation is pleasant
- Improved pain control by at least 50%?
- Treatment objective attained
  - Improved function
  - Improved vascular studies
  - Improved physical exam

What is a successful trial?

Successful Long-Term Outcomes of Spinal Cord Stimulation Despite Limited Pain Relief During Temporary Trialing

John C. Oakley, MD* • Elliot S. Krames, MD† • John Stamatos, MD‡ • Allison M. Foster, PhD†

What is a successful trial?

• 12 subjects who “failed” temporary trial because they reported less than 50% pain relief
• Nonetheless implanted with permanent SCS
• 5 because they explicitly stated that the trial provided substantial benefit to their lives that was not captured in the reported VAS score
• The others were implanted because of perceived significant benefit sufficient to warrant implant despite only moderate changes in VAS

Only 4 never reported > 50% pain relief, none withdrew
“VAS scores should not be considered the definitive predictive factor for later success with SCS”
Trial Considerations

• **Totally Percutaneous**
  - Can place in fluoroscopy suite
  - Shared approach to implantation
  - Must once again position lead in O.R.

• **Tunnel at the time of the trial**
  - Easily connected if trial is a success
  - Must return to the O.R if trial is unsuccessful
  - Increased infection rate?

Percutaneous Leads

• Catheter style
• Minimal or no sedation
• Trial and implant arrays are the same
• Less invasive, easy removal of trial lead
• Flexible lead positioning
• More prone to migration?¹
• Cylindrical electrodes


Practice of David L. Caraway, MD, PhD. Center for Pain Relief at St. Mary’s, Huntington, WV.
Surgical Leads

- Unidirectional
- Placed under direct vision via incision (laminectomy)
- Anchored at insertion site
- Stable multi column array
- Unidirectional field
- More invasive, requires surgery to remove or replace
- Lead fracture, migration occurs

Tunneled trials

*Infection Rate of Spinal Cord Stimulators After a Screening Trial Period. A 53-Month Third Party Follow-up (2004-2008)*

- N = 84 patients
- Two stage implant with trial phase lasting 1-3 weeks
- One infection occurred during trial, 3 after second stage
- 4.8% infection rate compared favorably to previous survey of long term trial (7.5%)

How long should a trial last?

• Reported trial duration varies significantly, from a few minutes to 65 days \(^1,2\)
• It has been suggested that longer trials are more predictive of long term success\(^3\)
• However prognostic values of trial duration have not been studied prospectively.

How long should a trial last?

- Retrospective study to compare an acute 15-min on table screening to a prolonged five-day trial in 54 patients.
- Success defined as >50% pain relief,
- Follow up (9.4 m +/- 1.5m)

<table>
<thead>
<tr>
<th>Period of observation</th>
<th>Patients with &gt;50% pain relief</th>
<th>Positive predictive value (PPV)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>during screening</td>
<td>long-term</td>
</tr>
<tr>
<td>Acute screening</td>
<td>55/64</td>
<td>31/38</td>
</tr>
<tr>
<td>Prolonged screenings</td>
<td>47/52</td>
<td>31/36</td>
</tr>
</tbody>
</table>

\(^{abc}\)Spearman Rank Correlation Coefficient (SRCC) = 0.462, \(p < 0.01\);
\(^{bc}\)SRCC = 0.462, \(p < 0.01\);
\(^{cd}\)SRCC = 0.465, \(p > 0.05\);
\(^{d}\)SRCC = 0.433, \(p < 0.01\).

North noted in an accompanying editorial that “statistical significance does not always translate to clinical significance”

- Success rates (90-98%) were much higher than that reported in the literature (75-80%)
- Acute trial predicted only 1/54 failure whereas the prolonged group predicted 5/52 failures
- Ability of screening protocol to predict failure more important
What is an appropriate trial to implant ratio?

- Literature generally reports rates of 65 – 80%
- Rates vary somewhat based on specialty, nature of practice, site of service and geographic region
- National Medicare database: 45%
- Palmetto: 38%

This is not a good thing

How long should a trial last?

Prospective Analysis of the Trial Period for Spinal Cord Stimulation Treatment for Chronic Pain

Mahindra Chincholkar, MD*, Sam Eldabe, MD*, Roger Strachan, MD1, Morag Brookes, BSc*, Fay Garner*, Raymond Chadwick, ClinPsyD1, Ashish Gulve, MD*, Jill Ness*

How long should a trial last?

• N = 40 patients trialed
• Chronic pain at least six months
• 1 or 2 tunneled leads
• 4 surgical trial leads
• Asked to complete identical diaries at similar times of the day
• 3 – 28 day potential trial period

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRPS type I</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>CRPS type II</td>
<td>7 (17.5%)</td>
</tr>
<tr>
<td>Failed back surgery syndrome</td>
<td>14 (35%)</td>
</tr>
<tr>
<td>Neuropathic pain</td>
<td>7 (17.5%)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (5%)</td>
</tr>
</tbody>
</table>

Chincholkar et al - Diary

• Vas score for surgical pain and original pain
• 10 point satisfaction score
• “If you had to decide today would you like to proceed to stimulator implant”
  – Yes, no, unsure
• 3 consecutive “yes” answers – indicates decision to proceed
• 3 consecutive “no” answers – patient declines implant
• If 28 days reached without decision then considered a failure
Chincholkar et al

- All patients were able to make a decision by 15 days.
- 75% were able to reach a decision in 9 days.
- Majority made a decision in 5.27 days, mean 5.97 days.
- 75% of successful trials made a decision in 6 days compared to 10 days in the failed group (N=6, 15%).
Chincholkar et al

Mean (SE) visual analog scale (VAS) for original pain.

Chincholkar et al

Mean (SE) visual analog scale (VAS) for operative pain.
How long should a trial last?

- Patients with a failed trial took longer to make a decision and experienced prolonged surgical pain.
- Majority of patients with a successful trial experienced more than a 50% pain reduction.
- 7 days seems adequate to routinely select patients for permanent SCS.
- Individualization appears important.

Is acute stimulation adequate?

- Innovative technology to assess different SCS technology to perhaps “salvage” a failed trial.
- Stanton-Hicks on “you tube”.
- Often used to test perceived paresthesia quality in the office.
- Labeling is consistent with literature.
How long should a trial last?

• Some clear successes occur immediately
• Failures often take longer to uncover.
• It appears that the best evidence points towards a trial lasting several days but little value in exceeding 1 week.
• 50% VAS pain reduction should be considered only one factor in the decision making process

THE END

THANK YOU