Evidence Table

Clinical Area: Spinal cord stimulation.

Study Type: Randomized controlled trial.
Study Aim: To assess the long-term outcome in terms of quality of life (QoL) and survival of patients with severe angina pectoris treated by spinal cord stimulation (SCS) or coronary bypass surgery (CABG).

Outcomes

*Primary endpoint:* Effect of treatment on angina.
*Secondary endpoints:* Morbidity and mortality.

Design

- **Number of subjects:** N=104 (n=51 in the CABG group, and n=53 in the SCS group).
- **Description of study population:** Study participants were recruited from 1992-1995 in Sweden. Their mean age was 70.5 years, and 80% were men. Their mean left ventricular ejection fraction was 57.5% (range 19%-86%).
- **Inclusion criteria:** Men and women with severe angina pectoris despite optimal pharmacological treatment, not suitable for percutaneous coronary angioplasty, and with an increased risk of complications (according to Higgin’s scoring system for estimation of pre-operative risk), and no proven prognostic benefit from CABG.
- **Exclusion criteria:** Patients were excluded if they had a myocardial infarction within 6 months from enrollment, were considered unsuitable for CABG, unable to mange the SCS device, or unable to follow the study protocol.
- **Intervention:** SCS group: The SCS device was implanted under local anesthesia and X-ray monitoring. The electrodes were positioned in a location that would lead to parasthesia in the chest at the location of the patient’s angina. The stimulation of the system was switched on and off, and increased or decreased by the patient. CABG group: Patients apparently underwent the routine CABG surgery.
- **Source of outcome data (e.g. patient self-report, doctor report, lab results):** Validated questionnaire to assess QoL (the generic NHP, and disease specific QLQ-AP), data from patient records and central registers.
- **Length of follow-up:** 4.8 years.

Validity:

- **Appropriate randomization procedures?** Yes.
- **Treatment/control groups comparable at baseline?** Yes.
- **Blinding:** No
- **Other than intervention, was care/follow-up similar in each group?** Yes.
- **Adequate compliance with intervention?** Yes.
- **Sufficient statistical power?** Not discussed.
Intention to treat analysis? Yes.
Completeness of follow-up: 85.5% complete.
Industry funding? Apparently none.

Conclusions regarding validity of methods:
The study had generally valid methodology, however it was relatively small, and the authors did not discuss if they performed any power analysis.

Results:

QoL (NHP* and QLQ-AP**) (presented in a chart in the study)

• Difference between QoL before intervention and after six months of SCS/CABG P<0.001. Difference was still significant after 4.8 years.
• Difference between 6 months and 4.7 years was not significant (NS).
• Difference between SCS and CABG at baseline NS
• Difference between SCS and CABG after intervention NS

*Nottingham Health Profile, a generic questionnaire that measures any health related quality of life. It consists of 2 parts: Part I includes 38 statements that examine energy, pain, emotional reaction, sleep, social isolation and physical mobility. Part II deals with 7 aspects of daily life work, ability to perform tasks at home, social life, home relationships, sex life, holidays, and hobbies.
** Quality of Life Questionnaire-Angina Pectoris is a disease specific questionnaire. It assesses the impact of anginal symptoms on the quality of life. The lower the score the greater is the impairment.

Survival

<table>
<thead>
<tr>
<th>Survival rate</th>
<th>SCS (n=53)</th>
<th>CABG (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 years after randomization</td>
<td>84.9%</td>
<td>76.5%</td>
</tr>
<tr>
<td>5 years after randomization</td>
<td>75.5%</td>
<td>68.6%</td>
</tr>
</tbody>
</table>

60% of the deaths were cardiac with no significant differences between the two groups.

Medication use after the intervention*

<table>
<thead>
<tr>
<th></th>
<th>SCS (n=53)</th>
<th>CABG (n=51)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short acting nitrates</td>
<td>21</td>
<td>13</td>
<td>25.5</td>
</tr>
<tr>
<td>Long acting nitrates</td>
<td>36</td>
<td>8</td>
<td>15.7</td>
</tr>
<tr>
<td>B-blockers</td>
<td>43</td>
<td>24</td>
<td>47.1</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>20</td>
<td>8</td>
<td>15.7</td>
</tr>
<tr>
<td>Mean number of drugs/patient/day</td>
<td>4.9</td>
<td>3.2</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*Only those with significant differences are presented in the table.

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• The difference between the two groups before the intervention was not significant
• For the SCS group the only significant decrease observed in drug consumption after vs. before the intervention was that for the use of short acting nitrates.
• For the CABG group the comparison between pre and post procedures shows a significant decrease in the use of short and long acting nitrates, beta-blockers, and Ca channel blockers.
• There was no significant difference between the two treatment groups in the use of aspirin, anticoagulants, diuretics, digoxin, lipid lowering drugs, or antidiabetics.

Authors’ Conclusions:

The authors concluded that both spinal cord stimulation and coronary artery bypass grafting are considered as effective treatment options for patients with severe angina and who are at an increased surgical risk. They indicated that the quality of life improvement with both interventions was long lasting, and that survival at 3 and 5 years were comparable between the two groups.

Reviewer’s Conclusions:

The trial was randomized, controlled, and had clinically important outcomes. However, due to the nature of the intervention it was unblinded, it was relatively small, and may have had insufficient power to detect statistically significant differences between the two intervention groups. No comparison was made to a group receiving pharmacological treatment only. The results of the study show that there was a significant improvement in the quality of life in the two groups after undergoing the interventions. The differences in the observed improvement in quality of life and survival were not significant between the two interventions. The study was not designed as equivalence study, and the absence of significant difference does not necessarily indicate that the two treatments are comparable or equivalent.