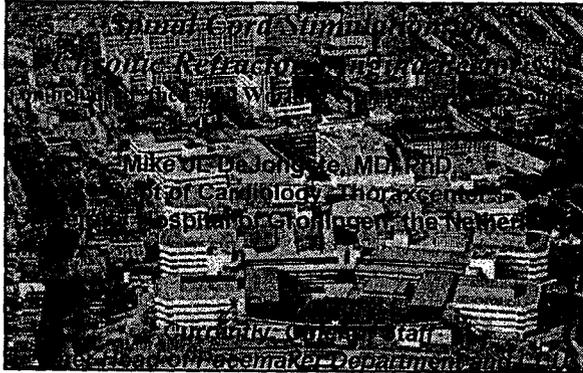


0913 '00 APR -7 A9:38



**Working Group Neurocardiology Groningen  
(Clinical Organization)**

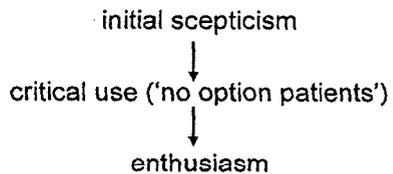
Dept Cardiology  
M DeJongste; R Hautvast; G Jessurun;  
A vd Sluis; O Klompstra

Dept Neurosurgery  
MJ Staal; JJ Mooij

Pain Center & Dept Anesthesiology  
A Durenkamp; J Ribbers; M van Wijhe;  
WJ Meyler; G Versteeg



**Rationale for Electrical Neuromodulation in  
Chronic Refractory Angina Pectoris Patients**



**team approach (F.up) + sound indication**

**Focus on SCS after > 1500 implants**

- ✓ An effective and reversible therapy
- ✓ A safe (cardioprotective) therapy
  - low complication rate
  - anginal pain is not concealed during an A.M.I.
  - morbidity & mortality are not adversely affected
- ✓ The underlying mechanism of action through which SCS acts, appears to be related to reduction in myocardial ischemia

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**Spinal Cord Stimulation for Angina Pectoris**

Defining chronic refractory angina pectoris

Procedure of SCS

Clinical studies

Safety

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**Chronic Refractory Angina Pectoris is defined as:**

severe (class III-IV NYHA) *angina pectoris*,  
 resulting from (significant) *coronary artery disease*,  
 with *reversible* myocardial ischemia,  
*unresponsive* to standard antiischemic therapies.

(Jessurun et al. *Pain Reviews* 1997;4:89-94 & Schoebel et al. *Am J Cardiol* 1997;134:587-602)

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### Baseline Characteristics

(Am Heart J 1997;134:587-602 and Heart 1999;82:82-9)

- **Demographics**
  - gender > 70% male
  - age ± 62 years
- **Cardiovascular status**
  - History of c.a.d. > 10 years
  - 3 VD 68%
  - LVEF > 40% 76%



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### Spinal Cord Stimulation for Angina Pectoris

*Defining chronic refractory angina pectoris*

**Procedure of SCS**

*Clinical studies*

*Safety*



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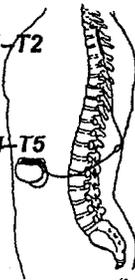
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### Lead & SCS Location

The electrode tip is commonly at **T1-T2**

Lead entry is commonly at **T4-T5**



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### **SCS Stimulation Protocol**

✓ Patients are instructed to stimulate 3 x 1 h  
(Sweden: 4 x 2 h; Italy: continuous) /  
day + during an anginal attack

Output            individually (0 - 10, 5 V)

✓ Pulse width    210 us

✓ Frequency      30 - 80 Hz



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### **Spinal Cord Stimulation for Angina Pectoris**

*Defining chronic refractory angina pectoris*

*Procedure of SCS*

**Clinical studies**

*Safety*



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### **Methodological Problems Concerning Study Design in Neuromodulation**

SCS therapy requires paresthesias

No real placebo for neuromodulation

Stimulation artefacts on the ECG



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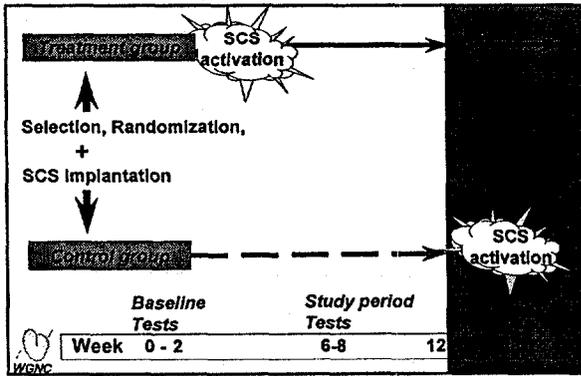
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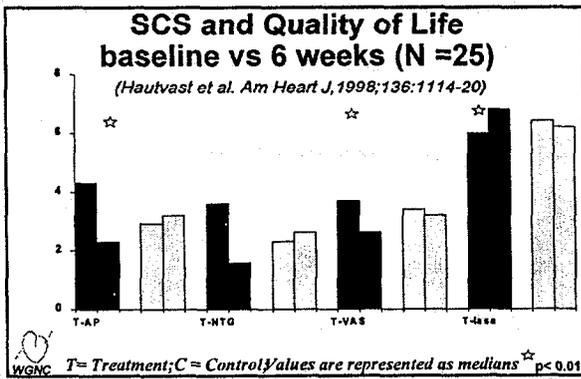
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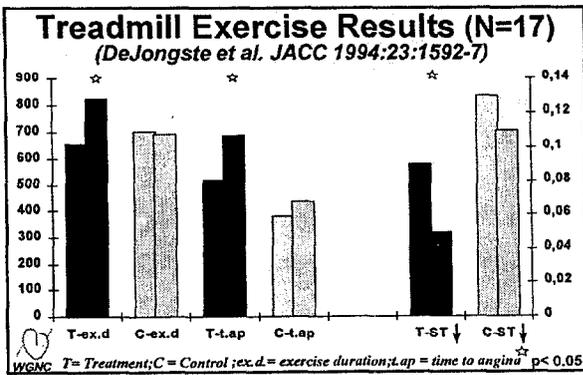
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**>100 articles (Open, Randomized \* etc)**

Murphy & Giles	Pain,	1987	10
Mannheimer <i>et al</i>	Br Heart J,	1988	10
Augustinsson <i>et al</i>	PACE,	1989	20
Gonzalez-Darder	Stereotact F.Neuro	1990	12
Eliasson <i>et al</i>	Coronary Art Dis	1993	12
Mannheimer <i>et al</i>	Br Med J	1993	20
Sanderson <i>et al</i>	Eur Heart J	1994	23
Andersen <i>et al</i>	Br Heart J	1994	50
DeJongste <i>et al</i>	J Am Coll Cardiol	1994	17*
Mannheimer <i>et al</i>	Circulation	1998	103*
Hautvast <i>et al</i>	Am Heart J	1998	25*
González-Darder	Neurosurg Quarterly	1998	23
TenVaarwerk <i>et al</i>	Heart	1999	517



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**Antiischemic Effects of SCS**

**Exercise stress testing**

↑ exercise capacity + ↓ ST-segment depression

**Ambulatory ECG recording**

↓ ST-segment depression (TIB)

**Right Atrial Pacing**

↓ lactate production + ↓ ST-segment depression

**Flow studies**

↑ coronary blood flow in apparently normal c.a.

**PET studies**

redistribution in coronary perfusion



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**Spinal Cord Stimulation for Angina Pectoris**

*Defining chronic refractory angina pectoris*

*Procedure of SCS*

*Clinical studies*

**Safety**



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### Safety aspects of SCS

- √ Does SCS mask anginal pain ?
- √ Effect SCS on morbidity & mortality



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### Patient MM

#### Medical History

1996: SCS implantation with excellent result  
1997: Patient experienced angina for 30 minutes.  
SCS and short-acting nitrates gave no relief.

She reported to hospital for help.

An anterolateral AMI was diagnosed and treated within 1 1/2 h (damage was mild)



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### SCS does not conceal the Anginal Pain during an Acute Myocardial Infarction

*Anderson C et al.* Br Heart J, 1994;71:419-21 (N=10)  
*Sanderson JE et al.* Eur Heart J, 1994;15:810-4 (N=2)  
*Jessurun GAJ et al.* Cor Artery Disease, 1997;8:33-7 (N=2)  
*González-Darder JM.* Neurosurg Q., 1998;8:16-23 (N=6)  
*Murray S et al.* Heart, 1999;82:89-92 (N=3); UAP (N=6)  
*Grecco et al.* Pace, 1999;22:26-32 (N=3)



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### Safety aspects of SCS

- √ Does SCS mask anginal pain ?
- √ Effect SCS on *morbidity & mortality*




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### Characteristics of Patients Treated with SCS for Refractory Angina (*Heart 1999;82:82-9*) Outcomes after 2-year follow-up (N=517)

**NYHA class** improved from 3.5 to 2.1 ( $p < 001$ )

**Mortality**

Annual all-cause mortality (cardiac) 7% (5%)  
 In deceased an AMI had occurred in 24% vs 8%  
 Deceased admissions were 66% vs 37%



**L.V.E.F.,  $\beta$ -blocking agents, age and sex were (multi-variate) independent predictors of mortality**

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### ESBY (*Mannheimer et al. Circulation 1998;97:1157-63*) A 104 **high-risk patients** were (intention-to-treat) randomized: **Electrical Stimulation vs Bypass surgery**

1/2 yr Follow-up	CABG (# 51)	SCS (# 53)	p
Symptom relief	79.5 %	83.7	ns
Ischemia	0.009	ns *	0.005
Morbidity	14	7	ns
Mortality	7	1	0.02



\* All patients were exercised with SCS "off"

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**Conclusions (after > 1500 implants)**

- ✓ SCS is an effective and reversible therapy
- ✓ SCS is safe (cardioprotective)
  - low complication rate
  - anginal pain is not concealed during an A.M.I.
  - morbidity & mortality are not adversely affected
- ✓ The underlying mechanism of action through which SCS acts, appears to be related to reduction in myocardial ischemia



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