Long-term outcomes after replacement of percutaneous leads with paddle leads in patients with spinal cord stimulation systems

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Learning Objectives

1)Identify common indications of spinal cord stimulation, 2)Identify common causes of spinal cord stimulation failure, 3)Discuss the outcomes of replacement of percutaneous leads with paddle leads in patients with spinal cord stimulation systems and correlated factors

Introduction

Although the long-term outcomes for spinal cord stimulation (SCS) have been reported, long-term outcomes of patients who underwent revisions of the SCS with paddle leads are lacking. We report the long-term outcomes of 39 patients (40 leads) that had percutaneous SCS revised with a new paddle lead.

Methods

Baseline and follow-up mail-in questionnaires assessed pain and disability levels, somatotopical overlap between SCS-related paresthesias and areas of chronic pain, and overall satisfaction. Analysis was performed with regard to diagnosis, gender, age, duration of disease, number of surgical revisions, complications, and interval between surgeries.

Results

Indications for SCS

Failed back surgery syndrome (n=14) and complex regional pain syndrome (n=18) were the most common indication for SCS, followed by back pain (n=3), cervical pain (n=2), plexopathy (n=2) and "failed neck" surgery syndrome (n=1).

Causes of percutenous leads SCS failure

Insuficient coverage (n=17), lead migration (n=12), and hardware failure (n=9) were the most common causes of percutaneous SCS lead failure. Other causes were infection (n=1) and impossibility of percutaneous lead progression (n=1).

Pain outcomes reported with numerical pain scale before and after surgical revision with the paddle lead. Overall results reported as well as outcomes according to number of surgical revisions, diagnosis and gender

	Baseline pain score[a]	Last follow up score[a]	Pain score difference[b]	Pain score difference (%)[b]	*P*-value[c]	*P*-value[d]
Overall pain	8.5 (8–9.8)	6 (4–8)	- 2.2 (2.2)	- 25% (27%)	< .001	n.a.
Number of surgical revisions						
Single revision (SR)	9 (8–9.5)	7 (4–8)	- 2.5 (2.4)	- 28% (28%)	< .001	.66
Multiple revisions (MR)	8 (7–10)	6 (4–8)	- 2.1 (2.3)	- 24% (28%)	.006	
Diagnosis						
FBSS	8 (7–9)	7 (4–8.3)	- 1.8 (2.1)	- 22% (25%)	.009	.40
CRPS	9 (7.8–10)	6 (4–8)	- 2.5 (2.6)	- 28% (31%)	.001	
Gender						
Male	8 (7–9)	5 (4–7)	- 2.6 (2.2)	- 31% (27%)	<.001	.28
Female	9 (8–10)	7 (4.5–8.5)	- 1.9 (2.3)	- 20% (28%)	.002	

[a]Median (interquartile range); [b]Mean (standard deviation); [c]within group *P*-value; [d]between groups *P*-value
FBSS: failed back surgery syndrome; CRPS: complex regional pain syndrome; n.a.: non-applicable

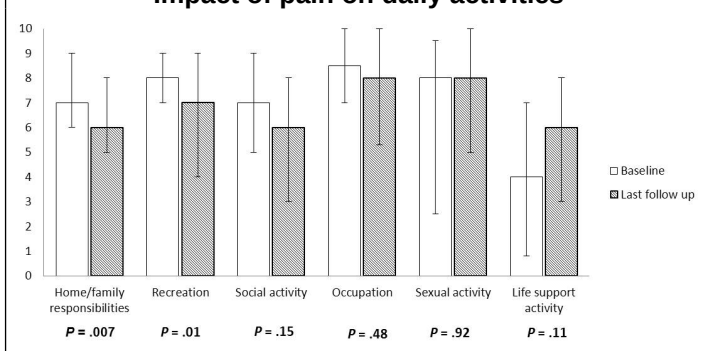
Outcomes

After surgical revision, 20 patients (50%) had at least 3 point reduction in the numerical rating scale. Greater pain reduction was correlated with better coverage (Spearman's rho= –0.48; P = .001). However, pain reduction was not correlated with diagnosis (P = .40), gender (P = .28), age (r = -0.08; P = .60) or duration of disease (Spearman's rho= 0.2; P = .20). Coverage area was greater in patients with a single revision (median: 100%; interquartile range: 71–100%) than patients with multiple revisions (median: 50%; interquartile range: 18–75%) (P = .01). Good satisfaction was reported by 25 patients (62.5%) who indicated that they would undergo the procedure again in order to achieve the same results. These patients had significantly greater pain reduction (P = .001), better coverage (P = .002) and shorter time interval between percutaneous and padlle implants (P = .01) than patients who reported otherwise.

Patient satisfaction

	n (%)	Pain score difference[a]	*P*-value[b]	Coverage[c]	*P*-value[b]	Implantation interval[c]	*P*-value[b]
Would you undergo surgery again in order to get the same pain relief you have now?							
Yes	25 (62.5%)	- 3.1 (2.1)	.001	75% (50–100%)	.002	9 (4–15)	.01
No	15 (37.5%)	- 0.8 (1.7)		13% (0–67%)		24.5 (12–40.8)	
Is stimulation working and covering the area of pain?							
Yes	31 (77.5%)	- 3.0 (2.0)	< .001	75% (50–100%)	< .001	11 (5–32)	.38
No	9 (22.5%)	0.4 (0.7)		0% (0–31.5%)		16.5 (9.3–34)	

[a]Mean (standard deviation); [b]Between groups *P*-value; [c]Median (interquartile range)
Implantation interval: number of months between cylindrical and paddle lead implantation



Patients were asked to rate disability among six spheres of function

The mean differences (SD) in disability scores before and after surgical revision were found to be significant for home/family responsibilities (P = .007), with a mean reduction (SD) of 1.4 points (2.4), and for recreation scores (P = .01), with a mean reduction (SD) of 1.7 points (3.3). The mean differences (SD) for the other spheres of function were not significant: -0.9 points (3.4) for social activity (P = .15); -0.4 points (2.5) for occupation (P = .48); +0.6 points (4.1) for sexual activity (P = .92) and +1.3 points (3.3) for life support activity (P = .11).

Complications

The most common causes of paddle SCS failure were insufficient coverage (n=5; 12.5%), hardware failure (n=5; 12.5%), and migration (n=2; 5%). One patient had a superficial wound dehiscence without infection that was treated with wound re-exploration. No other major complication occurred.

Conclusions

Replacement of percutaneous leads with paddle leads is an effective and safe procedure in patients with failed spinal cord stimulation and it is more effective in patients who have undergone no more than one prior revision.