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UNILATERAL VERSUS BILATERAL TINED LEAD STIMULATION IN PATIENT'S SELECTION FOR SACRAL NERVE STIMULATION

Hypothesis / aims of study

Since the marketing of the percutaneous permanent tined lead (PPTL), the role of the percutaneous nerve evaluation (PNE) has been questioned. Many centers rely solely on the PPTL instead of the PNE as a screening tool because it is believed to be a better predictor of success. Furthermore, there are currently mixed results on the better outcome using bilateral PPTL for patient's selection and in regard to treatment efficacy. The objectives were to evaluate whether the permanent lead is definitely superior to PNE as a screening tool and to determine whether bilateral PPTL stimulation is superior to the unilateral stimulation for patient's selection and treatment efficacy.

Study design, materials and methods

The patients underwent a PNE and were subsequently implanted with bilateral PPTL. Each lead was stimulated unilaterally for a one week period and then bilaterally for another week. Patients who improved by more than 50% were then implanted with the pulse generator which was either connected to both electrodes (PrimeADVANCED®) or only to one (InterStim®) while the other lead was buried in the subcutaneous fat based on the patient's best therapeutic response. The same test stimulation was repeated at 6 and 12 months follow-up in order to verify the sustained benefit of the stimulation. .

Results

Twenty-four patients were recruited and underwent a PNE which was successful in 12 of them (50%). Four patients were excluded from the study following the PNE, 3 because of personal preference and 1 because of a newly discovered myelomeningocele. The PPTL resulted in a therapeutic benefit in 95% (19/20) of the patient. Of these, 10 (52.6%) showed a better relief of symptoms using bilateral stimulation than with unilateral stimulation only. Three primeADVANCED® devices were removed during the first 6-month of follow-up. One was removed because of intractable generalized pain, 1 because of an infection and 1 one because device erosion secondary to a significant weight reduction. After 6-month follow-up, 14 of the 16 patients reported being significantly improved with the sacral nerve stimulation and the voiding diaries confirmed this improvement. The 2 failures were due to a damage electrode and their devices were reprogrammed. Sixteen patients completed the 12-month follow-up and 15 of them were still subjectively improved. The therapeutic benefit of bilateral stimulation over unilateral stimulation in the patients with the primeADVANCED® device was confirmed at 6 and 12-month.

Interpretation of results

The PPTL seems to be a better predictor of progression to IPG than the PNE, although the PNE remains cheaper, less invasive and if successful, is also a good predictor of progression to IPG. Moreover, when compare to the literature, bilateral PPTL implantation does seem to provide a higher progression to IPG rate than the standard method. In addition, bilateral PPTL stimulation provides additional therapeutic benefit over unilateral stimulation in a subset of patients. Its therapeutic benefit seems to be sustained over a period of 1 year.

Concluding message

Bilateral PPTL seems to be a better screening tool than PNE and unilateral PPTL and provides a greater therapeutic benefit than unilateral stimulation in a small subset of patients.

Table 1 Deterministic Analysis

INTERSTIM vs. BoNT-A

	Incr. Cost			Incr. QALY			C/QALY		
	Mean	Low Range	High Range	Mean	Low Range	High Range	Mean	Low Range	High Range
1 year	$7,237	$7,574	$6,709	0.05	0.05	0.05	$144,067	$150,769	$133,558
2 years	$4,318	$4,884	$3,591	0.09	0.09	0.09	$44,837	$50,708	$37,288
4 years	-$651	$277	-$1,691	0.19	0.19	0.19	Interstim Dominant	$1,436	Interstim Dominant
5 years	-$2,775	-$1,701	-$3,941	0.24	0.24	0.24	Interstim Dominant	Interstim Dominant	Interstim Dominant
10 years	-$9,402	-$7,698	-$11,129	0.51	0.51	0.51	Interstim Dominant	Interstim Dominant	Interstim Dominant

INTERSTIM vs. OMT

	Incr. Cost			Incr. QALY			C/QALY		
	Mean	Low Range	High Range	Mean	Low Range	High Range	Mean	Low Range	High Range
1 year	$8,878	$8,812	$9,008	0.19	0.19	0.19	$45,999	$45,655	$46,672
2 years	$5,888	$5,847	$6,029	0.38	0.38	0.38	$15,130	$15,024	$15,491
4 years	$348	$335	$523	0.76	0.76	0.76	$455	$438	$684
5 years	-$2,233	-$2,236	-$2,039	0.94	0.94	0.94	Interstim Dominant	Interstim Dominant	Interstim Dominant
10 years	-$11,447	-$11,347	-$11,246	1.76	1.76	1.76	Interstim Dominant	Interstim Dominant	Interstim Dominant

Table 2 Probabilistic Analysis

(Willingness-To-Pay = $50,000)

INTERSTIM vs. BoNT-A

	% < C/E threshold		
	Mean	Low Range	High Range
1 year	0.50%	0.10%	0.40%
2 years	26.70%	21.60%	48.60%
4 years	94.40%	95.60%	93.90%
5 years	93.20%	94.60%	89.40%
10 years	85.80%	88.60%	77.70%

INTERSTIM vs. OMT

	% < C/E threshold		
	Mean	Low Range	High Range
1 year	17.90%	22.00%	9.40%
2 years	99.90%	99.80%	100.00%
4 years	99.60%	99.60%	100.00%
5 years	99.60%	99.60%	100.00%
10 years	64.70%	61.40%	78.00%

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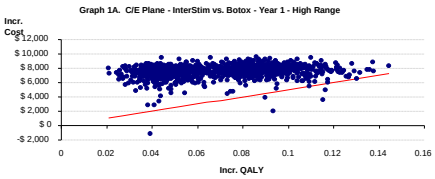

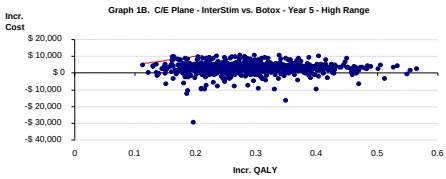

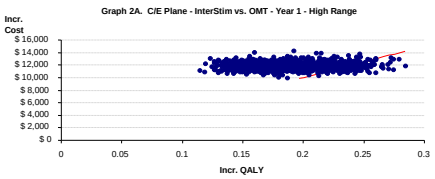

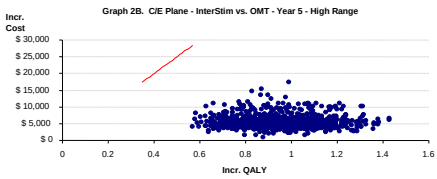

Disclosures

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Commitee of Sherbrooke. University Hospital Centre and Sherbrooke University)) **Helsinki:** Yes **Informed Consent:** Yes