ADVANCES IN NEUROSURGERY 3:

Brain Hypoxia, Pain

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Control of Pain by Electrical Stimulation
A Clinical Follow-Up Review

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Introduction

Clinical results of electrical stimulation therapy for acute and chronic pain are continuing to accumulate. While the mode of action remains the subject of theory, successes obtained with both cutaneous and implanted stimulating devices lead to a better understanding of the mechanisms involved and better use of these techniques. The collective clinical data reported here were obtained from over 25 neurosurgeons cooperating in pain-treatment study groups. Cases were collected and analyzed by follow-up correspondence to determine the lasting results of transcutaneous, dorsal column, peripheral nerve and direct brain stimulation devices. The patient-scoring criterion form used is presented and results are reported for each of the four techniques used in this study. These findings and their implications are, therefore, a composite of the present state of the art of pain control by electrical stimulation as practiced by a number of neurosurgeons in North America.

Method of Study

The management of acute and chronic pain is a decidedly important phase, and a very difficult one, of medical care. There have evolved a number of materials and methods for the medical, surgical and psychiatric management of patients having acute or chronic pain. Electrical stimulation may now be added as an additional method. Although the concept and practice of electrical stimulation for pain control is rooted in history, it is only since the development of the "gate control theory" by MELZACK and WALL in 1965 that a new and refreshing look at the potential use of electrical stimulation for pain control has occurred (1). Following the first clinical implantation of a dorsal column stimulation device in 1967 by SHEALY (2, 3), new techniques and devices utilizing this mode of therapeutic management have emerged at an ever-increasing rate. The results have ranged from spectacular to disappointing. There is now accumulating a considerable evidence fo the neurophysiological basis of electrical stimulation in pain control, but much physiological and anatomical mystery persists. Nonetheless, this concept has provoked more intensive study of the anatomy and physiology of sensory mechanisms in the spinal cord than any other clinical therapeutic mode (with the possible exception of the older destructive techniques for pain control). One of the most attractive aspects of electrical stimulation for pain control lies in its non-destructive and reversible nature. If good results are not obtained either in a short or prolonged period of time, the removal of the device will in all cases (with the exception of rare complications resulting from pressure exerted on nerve or spinal cord by electrodes) return the patient to his pre-implantation state. Further,

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electrical stimulation may indeed somehow "re-train" or "modulate" the nervous system so that, in due time, the pain disappears without the need for further treatment.

This report contains the collective experiences of 25 neurosurgeons in North America who have utilized various modes of electrical stimulation for the control of acute and chronic pain. Four reports are included here: transcutaneous nerve stimulation, dorsal column stimulation, peripheral nerve stimulation, and direct brain (thalamic or internal capsular) stimulation. This work was done by study groups formed and supported by Medtronic, Incorporated, in order to further evaluate both the concept and the specific application of devices. The study group method brings together expert clinicians who may share experiences relevant to patient selection, screening criteria and methods, surgical techniques, problems, follow-up results, indications and contraindications, device and electrode design improvements, comprehensive pain management programs, drug detoxification, third party payment for devices and fees, etc. In the early stages of the development and application of new devices, there is a limited quantity of instruments available; the study group helps to "ration" the devices. Further, study groups help insure that the well controlled clinical studies are subjected to review by peers.

A number of patient evaluation forms have been developed but the most representative appears to be a series of questions which permit the scoring of a pain profile relative to five major criteria.[1] The scoring matrix shown in Table 1 was developed principally by PICAZA aided by SHEALY and RAY. In the questionnaires developed by Medtronic, Inc., to be filled out by the physician and by the patient, responses are arranged according to five criteria into grades ranging from 0 to 4. Since pain is a subjective, conscious process, and since the responses of patients to inquiry regarding their pains will always be highly loaded with subjective impressions, this pain profile and the associated questionnaires make a maximum attempt at objectifying (and quantifying) the very subjective nature of most pain syndromes.

At intervals, beginning prior to implantation or cutaneous stimulation treatment, and following therapeutic use of the corresponding devices, patients are asked to complete questionnaires from which the profile could be drawn each time. In many cases physician interviews and impressions were reduced to a scoring of the profile for comparative purposes. In conducting a post-therapeutic follow-up by mail, a great number of patients will not respond. Therefore, direct patient surveys must often be supplemented by having a member of our staff (a registered nurse skilled in the techniques of patient interview - and follow-up analysis) contact the non-responding patients by telephone in order to urge their completion of the form or, in order to obtain oral information sufficient to complete the scoring of the profile. All such subjective follow-up techniques may cast some doubt as to the reliability of results, but since the same group of people evaluated all the responding patients, and since these clinical assistants were not associated with the operating surgeon or treating physician, it is felt that this might have helped to remove some patient bias (where he might have desired to satisfy his clinician as to good results when there might not have been any).

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[1] Forms available from Medtronic, Inc.

Table 1. Pain profile scoring matrix

Grade	Daily duration of pain	Intensity of pain	Activity level	Drugs	Behavior
0	No pain	None	Normal	None	Normal - alert, cheerful, cooperative
1	Having pain up to 25% of time	Mild	Slightly restricted activity	Aspirin	Slightly disturbed - irritable, disagreeable, complaining, moody
2	Up to 50% of time	Discomforting	Moderately restricted	Sedatives tranquilizers	Moderately disturbed - dull, unhappy, anxious, uncooperative
3	Up to 75% of time	Distressing	Severely restricted	Hypnotics Darvon	Quite disturbed - quite depressed, moderately withdrawn, bitter, desperate
4	Up to 100% of time	Horrible or excruciating	Incapacitated	Narcotics	Asocial - severely withdrawn, belligerent, combative, asocial, panic state

Table 3. Transcutaneous nerve stimulation for relief of chronic pain

Amount of pain relief reported after:	7 months of therapy			12 months of therapy		
	394 patients			78 patients		
	N	% of total		N	% of total	
Complete relief (100%)	26	7%		7	9%	
Major relief (75-99%)	68	18%	63%	8	10%	55%
Significant relief (50-74%)	147	38%		28	36%	
Minor relief (25-49%)	62	16%		15	19%	
Minimal relief (1-24%)	55	14%		16	21%	
No relief (0%)	26	7%		4	5%	
Total	394	100%		78	100%	

Transcutaneous Nerve Stimulation

In this collective study, 396 chronic pain patients were followed. Their average age was 48 years, ranging from 18 to 80.

The results of the average seven-month duration of use for various pain etiologies is presented in Table 2.

Table 2. Transcutaneous nerve stimulation for the relief of chronic pain. 396 patients: 7 month average time device used (direct patient survey)

Etiology	N	Successful % (50-100% relief)		Unsuccessful % (0-49% relief)	
Low back syndrome	29	19	66%	10	34%
Multiple op-low back	125	69	55%	56	45%
Post trauma-low back	18	11	61%	7	39%
Post trauma-thoracic	5	2	40%	3	60%
"Other" - upper back	4	3	75%	1	25%
Multiple op-cervical	6	5	83%	1	17%
Post trauma-cervical	8	7	88%	1	13%
Degenerative spine	14	9	64%	5	36%
Arthritis	14	10	71%	4	29%
Cancer	3	3	100%		
Headache	5	4	80%	1	20%
Causalgia	5	4	80%	1	20%
Postherpetic	5	3	60%	2	40%
Neuroma	3	3	100%		
Amputation/phantom	10	8	80%	2	20%
Unknown	72	44	61%	28	39%
Other	53	37	70%	16	30%
Total	379	241	64%	138	36%

Seventy-eight patients who were using the device at the end of 12 months responded to a follow-up questionnaire. The comparison of overall results between these two groups are given in Table 3, where it may be noted that patients showing 50% or better pain relief comprise 63% of the patients in the seven-month group and 55% of the patients in the twelve-month group. Since TNS is a very simply applied external device, it is indeed important that in this collective study the success was quite high, considering the nature of the pain and the fact that a great number of cases had pain over long periods of time, even years, prior to treatment by electrical stimulation.

In general, patients who show significant, major or complete relief of pain, also show improvement in nearly all of the other criteria of the pain profile. Indeed, PICAZA (4) has found that when patients show improvements in all elements of their profile with the exception of 1 or 2, then the validity of their results may be questioned. (The only possible exception to this lies in the use of drugs where one may find a disproportionately high percentage of patients having major relief of pain who, nevertheless, continue to use drugs in grades 3 or 4.)

Nonetheless, the technique is so innocuous and easily applied that the method is worthy of trial in a great number of pain cases, not only as a method of screening for subsequent implantation, but also as the sole mode of therapy. TNS is often combined with other therapeutic means in a comprehensive pain program and a number of clinics have reported series ranging up to as many as 3,000 cases whose overall results appear to be similar to those given here (5, 6, 7).

Further, a very large population of patients exist who have been treated for *acute* pain by transcutaneous nerve stimulation but no firm statistics are available at this time.

In general, the acute applications show an overall efficacy as high as 80% (8) as compared to approximately 25% efficacy for chronic pain cases over a long term period (9). The acute applications include traumatic pain in limbs and joints, postoperative pain management following abdominal or thoracic procedures, acute episodes of headache, rehabilitation (such as in range of motion exercises) and as an adjunct to local anesthesia for various surgical and dental procedures.

Of course, we can assume that a large number of patients who initially had tried the treatment, dropped out before seven months and an even larger number by 12 months; they did so because of receiving little or no relief of their pain.

Dorsal Column Stimulation

The patients reported in this collective series, as shown in Table 4, comprise a large number of pain etiologies. Two hundred and sixty-six patients are reported in a follow-up period having an average of 18 months implantation. These patients were divided into two groups. The first group was an earlier collection of 481 cases in which only 39% of the questionnaires were returned completed. The majority of the cases either did not return their questionnaires or they were returned incomplete. A second group of 119 cases returned 66% (78) of the questionnaires. This represents a combined total of 266 patients who responded out of a total of 600 cases sent questionnaires. Since the time of collection of these data, a number of the patients have been followed by telephone and by additional correspondence and it appears that the non-responding patients probably fall fairly equally divided between those patients who have not been adequately relieved and those patients who have (This will be the subject of a subsequent publication). In general, the results show that approximately 50% of the cases had 50% or better pain relief over 18 months of average implantation time. More recently, the use of acute and relatively chronic indwelling electrodes, mostly placed extradurally for longer term screening, has resulted in an overall improvement in patient selection. It is anticipated that this may well result in an elevation of the general efficacy of this technique (10, 11).

Peripheral Nerve Stimulation

In Table 5, one finds the combined results of 75 patients who responded. In general, this technique appears to have an efficacy similar to that of dorsal column stimulation for selected cases. It is most often used for low-back syndromes with pain radiation into one leg. The large number of sciatic implants reflects this principal application.

Table 4. DCS implant survey of U.S. study group members. Average follow-up period of 18 months, total of 266 patient respondents

Diagnosis/Etiology	Successful (50-100% pain relief)		Unsuccessful (0-49% pain relief)		Total
	N	(%)	N	(%)	
Low back pain described as:					
1. Low back syndrome	27	(45)	33	(55)	60
2. Unsuccessful disc surgery	39	(53)	34	(47)	73
3. Adhesive arachnoiditis	25	(45)	30	(55)	55
4. Degenerative disc disease	4	(50)	4	(50)	8
Subtotal low back	95	(48)	101	(52)	196
Trauma	6	(35)	11	(65)	17
Cancer	0	(0)	3	(100)	3
Paraplegia	1	(50)	1	(50)	2
Post-amputation	2	(40)	3	(60)	5
Peripheral nerve syndrome	1	(50)	1	(50)	2
Neuroma	1	(100)	0	(0)	1
Postherpetic neuralgia	0	(0)	2	(100)	2
Multiple sclerosis	2	(100)	0	(0)	2
Other	7	(44)	9	(56)	16
Unknown	2	(50)	2	(50)	4
Total	117	(47)	133	(53)	250

Table 5. PNS patient survey of U.S. study group members. 75 patient respondents

Electrode placement vs. pain relief:

Placement	Successful (50-100% relief)		Unsuccessful (0-49% pain relief)		Total
	N	(%)	N	(%)	
Sciatic	25	(71)	10	(29)	35
Ulnar	4	(44)	5	(56)	9
Occipital	4	(100)	0	(0)	4
Femoral	1	(34)	2	(66)	3
Brachial Plexus	3	(75)	1	(25)	4
Pudendal	1	(100)	0	(0)	1
Peroneal	1	(100)	0	(0)	1
Total	39	(52)	18	(24)	57[a]

[a] 18 patients (24%) have either had their PNS device removed or have discontinued its use.

Brain Stimulation

In Table 6, one finds a resumé of 28 patients who are the total population of this one-year-average implant study. Under the column "Implant site", one also sees a listing of the pain etiologies treated by each particular implant technique. In general, this technique shows the highest degree of efficacy for relief of chronic pain of the techniques reported in this paper. The majority of these patients were treated by ADAMS and HOSOBUCHI (12)(both of San Francisco) and RICHARDSON (of New Orleans). This technique, while the most complex of those reported here, appears to affect far more directly the pathways of pain, and therefore the smallest electrical field has the greatest overall initial and lasting results.

Table 6. Brain stimulation for relief of chronic pain. 28 patients: 1 year average implant

Implant site	N	Successful % (50-100% relief)		Unsuccessful % (0-49% relief)	
Internal Capsule					
CNS lesions	11	9	82%	2	18%
PNS lesions	2	2	100%		
Sensory thalamic (VPM)					
Facial pain	4	3	75%	1	25%
Medial Thalamus (PVG)					
CNS lesions	1	1	100%		
PNS lesions	1	1	100%		
Cancer head	1			1	100%
Cancer trunk	4	4	100%		
LB syndrome	3	3	100%		
Brain stem					
Facial pain	1	1	100%		
Total	28	24	86%	4	14%

At 75-100% relief: 6 successes, CNS lesion, internal capsule stimulation; 2 successes, facial pain, VPM stimulation.

Discussion and Summary

Presented here are clinical results and follow-ups of cases comprising patients in the series of 25 neurosurgeons in North America. Reported are four modalities of therapy using electrical stimulation to control chronic pain. In general, the long term results using transcutaneous nerve stimulation for chronic pain were favorable in 63% and 55% of patients whose results were reported at the end of 7 and 12 months of therapy, respectively. Due to the rather selective nature of these cases, it is felt that these results compare favorably with those now being reported elsewhere which indicate that transcutaneous nerve stimulation may have an overall efficacy of about 25% of cases for *chronic* pain control. Approximately 80% of the cases with acute, traumatic or postoperative pain may be successfully managed with little or no additional medication while employing skin surface stimulation. Overall results for dorsal column and peripheral nerve stimulation indicate that about 50% of the patients will be helped by removing 50% or more of their pain for periods of time

ranging up to more than 18 months. Recent reports indicate that where the good results of dorsal column stimulation may show a decline in many cases, a number of these patients may be returned to good pain control if the electrode is moved to another site along the spinal cord. This appears to be often related to the development of fibrosis around the surface of the electrode with long term stimulation. A few cases similarly have been reported with peripheral nerve stimulation. These conclusions indicate that in all stimulation techniques, the relocation of electrodes should be considered before discontinuing the therapy entirely. Deep brain stimulation has the highest overall rate of success, although this method is applied in what are probably the most severe pain cases. In summary, this report, as well as others which are now appearing regarding the use of electrical stimulation for the control of acute and chronic pain, indicates that this is a viable therapy in selected cases that compares favorably with existing methods of treatment in the management of intractable chronic pain, particularly in relation to certain pain etiologies.

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The clinical study status reports containing the above information are available from Medtronic, Inc., as:

"Follow-Up Survey on Peripheral Nerve Stimulation Implants," NR503, July 12, 1974.

"Follow-Up Survey on Dorsal Cord Stimulator Implants," NR510, February 27, 1975.

"3583 Electrode Clinical Study Status Report," NR511, April 15, 1975.

Patient Use and Acceptance of the Neuromod™ Transcutaneous Nerve Stimulator, NR512, March 31, 1975.

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