

Neuromodulation: Technology at the Neural Interface

Non-CME Session Abstracts and Schedule



December 9- 12, 2007
Acapulco, Mexico



International
neuromodulation
society

8th world
congress



11th annual
meeting

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Sunday December 9
0700- 0707
Princesa Ballroom B-C (13)

1. Therapeutic effect of deep brain stimulation of the nucleus accumbens on refractory drug addiction: a case report

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Introduction

The mesolimbic dopaminergic (DAergic) pathway projecting from the ventral tegmental area (VTA) to the nucleus accumbens (NAC) may play a critical role in the initiation of psychological dependence on morphine. Bilateral ablating the nucleus accumbens has been demonstrated to be an effective treatment for drug addiction. But there are many concerns about the effects of producing irreversible lesions in neural centers such as food intake, sexual behaviour and probably a myriad other more mundane daily pleasures. In order to avoid these complications, DBS may be the best choice to prevent permanent damage of nucleus accumbens.

Materials and Methods

We report the bilateral nucleus accumbens DBS in a 24-year-old young man who has started intravenous heroin injections for five years. Treatment included UROD first, three days later, bilateral nucleus accumbens were implanted two electrodes for DBS. In UROD program. The patient was treated with naloxone(0.2mg/kg) under anesthesia. In DBS program the nucleus accumbens target coordinates were as follows: 7.5mm in front of the anterior commissural, 6mm below the midcommissural point, and 6.5mm lateral to the midline. the final stimulator settings: amplitude 2.5 volts; pulse width 90µsec; rate 145 Hz; electrodes monopolar C +, 1-, 3-.

Results

The patient has been followed-up for over two years, irregular randomly selected examination of urine samples and naloxone tests show that he has completely abandoned his drug usage without any ancillary treatment. He has even returned to full -time work for more than one year. One month ago, the stimulator was turned-off and the patient's condition was satisfactory. The temporary postoperative complication were clouding of consciousness, somniloquy and Urine incontinence, they were recovered within 2-3 days. While the insomnia recovered after about 4-5 months latter. WMS, WEIS-RC and MMPI before and after the DBS assessed by psychologist revealed that the patient's intelligence remembrance and personality were intact.

Conclusion

Our preliminary study demonstrate that deep brain stimulation of the nucleus accumbens has therapeutic effort on refractory drug addiction.

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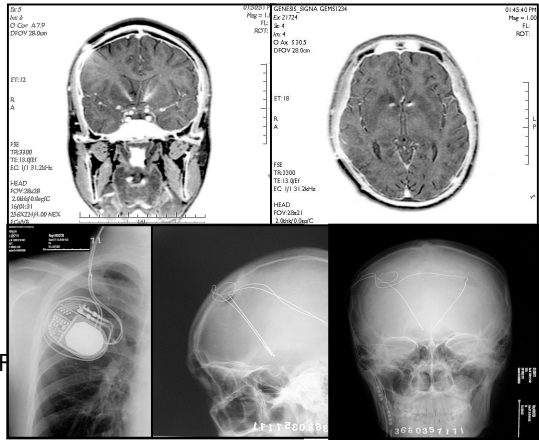
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Acknowledgements

The electrodes and the programmable pulse generators implanted in the patient are supported by Metronic, Inc.



Sunday December 9
0710- 0717
Princesa Ballroom B-C (13)

2. Deep brain stimulation in intractable epilepsy

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Introduction

Neuromodulation therapy using implantable electrical stimulation device has been applied for patients who are not considered as good as candidates for resective surgery recently. We analyzed clinical outcome after chronic deep brain stimulation of the subthalamic nucleus or anterior thalamic nucleus in intractable epilepsy.

Materials and Methods

We performed bilateral chronic deep brain stimulation in patients with intractable epilepsy, targeted at the subthalamic nucleus in 2 patients, and at the anterior thalamus nucleus in 6 patients. Three male and 5 female patients were included; their mean age was 27 years. None of them had the history of previous surgery for intractable epilepsy, except one with failed tailored resection.

Results

In patients with subthalamic stimulation, the seizure frequency was reduced by 21% and 25% at 34 months. In patients with anterior thalamic stimulation, the seizure frequency was reduced by 58%, 72%, 55%, 21%,



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81% at 18, 16, 13, 9 and 6 months after surgery, respectively. No adverse effects were observed after deep brain stimulation electrode insertion or stimulation .

Conclusion: Our clinical experience suggest that deep brain stimulation in intractable epilepsy may be effective and a safe alternative treatment. However outcome of deep brain stimulation in patients with intractable epilepsy was variable in our study. Therefore more larger patients series are required to identify the good candidates for deep brain stimulation and optimal stimulation paradigms.

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Learning Objectives

1. The efficacy and limitations of deep brain stimulation in patient with intractable epilepsy
2. The good candidates and target for deep brain stimulation in intractable epilepsy

Sunday December 9

0720-0727

Princesa Ballroom B-C (13)

3. Deep brain stimulation for pain: a 50 case experience.

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Introduction

Worldwide, 1300 patients have received deep brain stimulation (DBS) for chronic neuropathic pain refractory to drug treatments over the last four decades. However, failures to demonstrate efficacy adequately in clinical trials led to the procedure being refused FDA approval. Few centres worldwide have published findings from patients treated for pain by DBS during the last decade using current technological standards. Here we present our contemporary experience of DBS of the thalamus and periaqueductal gray.(1) We also propose and apply novel evidence-based methodology for evaluating outcomes in DBS predicated upon increasing the signal to noise ratio of efficacy versus disease natural history and obviating requirements for multi-centre randomised controlled trials.(2)

Materials and Methods

Prospective evaluation was undertaken of 50 patients with chronic pain treated by DBS at a single British neurosurgical centre from 1998 to 2006. Subjective reports and quantitative assessments of pain (Visual Analog Score and McGill Pain Questionnaire) and quality of life (Short Form 36 and Euroqol) were undertaken before surgery, during the postoperative week, at 1,3,6 months and 6 monthly intervals thereafter. Stimulator settings were recorded when changed together with pain scores. Conventional and novel statistical techniques were used to interpret the evidence.

Results

DBS is efficacious for pain after amputation, stroke, cranial and facial pain including anesthesia dolorosa. Other groups with multiple sclerosis, malignancy, failed back syndrome and trauma pain may benefit from DBS.

Conclusion

DBS is effective treatment for certain chronic pain aetiologies in carefully selected patients. Ethical and practical challenges can limit the translation of case series to randomised trials, however both N-of-1 trials and signal to noise ratios provide compelling evidence of efficacy auguring for their adoption in the field of pain surgery.(3)

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

References

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Acknowledgements

The authors are supported by the Norman Collisson Foundation, Charles Wolfson Charitable Trust and UK Medical Research Council.

Learning Objectives:

1. Discuss deep brain stimulation (DBS) as a re-emerging treatment for chronic pain
2. Identify useful outcome measures in evaluating DBS for pain
3. Describe novel methods for evaluating evidence in DBS and pain surgery

Sunday December 9

0730-0737

Princesa Ballroom B-C (13)

4. Automatical classification of microelectrode recording signals (MER) in deep brain stimulation of the subthalamic nucleus (STN)

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Introduction

MER has become a useful tool in deep brain stimulation procedures. However it is time consuming, sometimes difficult and depends very much upon the experience to interpret the signals in a correct way.

Materials and Methods

To support the surgical team in STN surgery, an automatical, computer based classifier was constructed. It consists of 3 levels. At the 1st level, the background activity is analyzed, at the 2nd, bursty or irregular signals are detected, based on single cell burst activity. At the 3rd level, the spike rate of duplicated intervals from levels 1 and 2 are analyzed.

The essential elements of this algorithm are different kinds of wavelet transformations to remove background noise, as well as to enhance certain signal properties.

Results

The classifier has been tested in 2134 MER traces from regular STN surgeries and compared in a blinded way with the results of an surgeon with high level experience in MER signal interpretation. The results of the automatical classifier were congruent in 95%.

Conclusion

Automatical online MER signal analysis of human STN signals is possible with high accuracy using a mainly wavelet transformation based algorithm. This may save time and may increase accuracy and objectivity mainly in DBS teams with less experience.

Learning Objectives:

Automatical classification of microelectrode recording signals in STN surgery is possible and reliable with this newly developed algorithm. This may increase the objectivity and reduce the operation time in DBS procedures.

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Sunday, December 9

0740-0747

Princesa Ballroom B-C (13)

5. Mechanisms of Deep Brain Stimulation in Parkinson's Disease

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Introduction

Two major factors are responsible for effects of chronic stimulation of various basal ganglia structures in Parkinson's disease – functional block and stimulation of the neural elements surrounding electrode's tip. They are equivalent to a lesion and adding noise to the system, correspondingly. Classical conceptual brain understanding cannot provide adequate explanation of deep brain stimulation mechanisms.

Materials and Methods

This theoretical research based on new conceptual understanding of the brain explains how both factors, lesion and noise, alleviate motor symptoms.

Results

The following ideas are the foundation for the explanation (Baev et al, 2002). The basal ganglia play the role of predicting system in motor cortico - basal ganglia - thalamocortical loop. It models a behavior of the body and an environment during motor control, i.e., it generates feedforward model. Dopaminergic neurons are a part of an error distribution system that provides the model with information about the quality of predictions. The lack of adequate error signals caused by the death of dopaminergic neurons leads to erroneous predictions. Wrong predictions result in pathological behavior. A case of wrong prediction is treated by the controlling system as if the controlled object was perturbed by an external force and the controlling system tries to correct its state. A basal ganglia lesion or its equivalent decrease resolution power of the predictive system. As a result, the controlling system becomes less reactive to errors in its predictions. A noise added to the controlling system has a double effect on it. The first consists in decreasing the sensitivity of the system to afferent and model signals. The second, the noise helps the system to slide down to the global minimum on the error surface, and the model becomes better tuned on the controlled object.

Conclusion

Described mechanisms of chronic stimulation of various basal ganglia structures is applicable to other neuromodulation therapies.

References

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Learning Objectives:

1. Deep brain stimulation mechanisms are perfectly explained based on new conceptual understanding of the brain. The latter includes neural network computational principle and generic functional organization of hierarchical neural systems controlling automatic animal motor behaviors.

Sunday December 9

0750-0757

Princesa Ballroom B-C (13)

6. Deep brain stimulation and external cardiac defibrillation in an animal model: Evidence for tissue damage?

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Introduction

Parkinson's disease patients with long term L-dopa syndrome benefit from deep brain stimulation. Other indications are movement disorders like essential tremor, dystonia and intractable pain syndromes. When the advanced life support algorithm demands cardio version or defibrillation in these patients, undesired effects of monophasic electroshocks might occur on brain tissue adjacent to the stimulation electrodes (e.g. thermal injury) but also on the stimulation device itself.(1,2)

Materials and Methods

The present animal study (n = 6 pigs) investigated the effects of repeated defibrillation (2x 200J (n = 1) and 2 x 360J (n = 5) at the implantation site of cerebral stimulation electrodes (Medtronic 3387 and 3389) and on stimulation device functionality (Medtronic Kinetra).

Results

Repeated defibrillation did not cause (thermal) injury at the implantation site of the cerebral stimulation electrodes in different stimulation combinations nor cause injury to the tissue adjacent to the impulse generator. Functionality of the stimulator device following defibrillation, however, ranged from normal to total loss of function.

Conclusion:

We show here that repeated external cardiac defibrillation is safe with regard to thermal injury of brain tissue adjacent to the cerebral stimulation electrodes and the impulse generator pocket. The electrode combination or bipolar versus monopolar stimulation shows no difference. When performing defibrillation, however, the greatest possible distance must be maintained to the stimulator device implantation site. Subsequent testing of the stimulator device's functionality after defibrillation is absolutely necessary.

References

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Learning Objectives:

1. Cardiac defibrillation is safe with regard to thermal injury of brain tissue adjacent to the cerebral stimulation electrodes and the impulse generator pocket.

Sunday, December 9

1630-1637

Princesa Ballroom B-C (13)

1. SCS in three different pathologies. 20 years experience

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David Abejón MD, FIPP

Introduction

The goals of the study are to value the effectiveness and security of the spinal cord stimulation (SCS) during 20 years of experience. The effectiveness is valued according to the type of pathology that suffers the patients, divided in 3 groups, failed back surgery syndrome (FBSS), peripheral vascular disease (PVD) and complex regional pain syndrome (CRPS) (1, 2, 3).

Materials and Methods

A retrospective observational study is made from 1983 to the 2002 analyzing the patients submissive SCS. The patients with 3 different diagnoses compare themselves. The degree of pain the patient according to one climbs verbal of 4 degrees (slight, moderate, intense and unbearable pain), and according to a visual analogical scale from 0 to 100 (where 0 is non pain and 100 are an unbearable pain). On the other hand the effectiveness of the stimulation is analyzed according to an own scale of 4 variables, nothing (0%), fair

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

(30%-49%), much (50%-79%) and total (80%-100%). The statistical analysis in the three groups' diagnoses is made by means of the test of square Chi to verify if significant difference in the degree of improvement among pathologies.

Results

The sample is compound of 260 patients, divided by group's diagnoses: in 98 patients with PVD, 65 with FBSS, 40 with CRPS and the rest with several diagnoses. The specialty that derived most frequently derived patients to the Unit during this period was Cardiovascular Surgery Service. The most frequent pain was the neuropathic pain and the final location of the electrodes most frequent was the thoracic. The improvement in global terms was of 64%. The use of the SCS in the patients with CRPS was made in 50% of the cases in the cervical zone and the rest in the thoracic. The improvement superior to 50% was obtained, in this group, 55% of the sample. The rate of complications was of 32%. The group with PVD diagnosis is made up of 98 patients with an improvement of 88% and one rate of complications of 17%. Finally the group with FBSS diagnosis is made up of 65 patients with an improvement near 51% with a rate of complications of 29%.

Conclusion

The study shows the experience during 20 years in SCS. All the results in our patients are similar to other authors, and the best of that are in PVD.

References

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Learning Objectives:

1. The scs is very success in PVD, in which we can reduce the numbers of amputations.
2. The scs in one of the best treatments in FBSS and the rate of success in CRPS are close to 80%.
3. We didn't have major complications with this kind of treatment.

Sunday, December 9

1640-1647

Princesa Ballroom B-C (13)

2. An Initial Evaluation of Subcutaneous Stimulation for the Treatment of Chronic Pain.

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Introduction

In the past four decades the use of electrical current to treat diseases has grown in both scope and application (1). The placement of leads in the subcutaneous tissue to modulate current of the nerve fibers is an area of new interest and excitement. Subcutaneous stimulation, also called peripheral nerve field stimulation, is often used to stimulate nerve fields that are not easily affected by stimulation of the spinal cord, nerve root or central nervous system(2). Areas that are often treated by this technique include the occiput, paravertebral tissues, parascapular zone, abdominal wall, groin, and chest wall. This abstract presents on initial results with these techniques.

The goal of this paper is to demonstrate the possibility of the effectiveness of subcutaneous technique to deliver precise current to areas that would not routinely be successfully stimulated by the conventional spinal cord stimulation method.

Materials and Methods

A prospective observational study was performed of patients undergoing subcutaneous peripheral nerve field stimulation from the period of January 2006 until December 2006. Nineteen patients with intractable chronic pain of non-cancer origin were treated by this method. In seventeen patients a simple quadrapolar lead was used for trialing. In the two patients with chronic pancreatitis octapolar(3) leads were used. Trials varied in length based on patient response and the need for reprogramming. In order to consider a trial

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

successful the target zone received paresthesia that gave significant pain reduction defined as 50% or more by the visual analog scale as well as significant degree of patient satisfaction. Once a successful trial was determined the patients were implanted permanently three weeks later. The waiting period was selected to assure the patient had ample time to consider the risk to benefit ratio and other alternatives. Table one shows the pain generators for these patients.

Results

The total number of patients offered enrollment into this analysis was nineteen. All patients agreed to be included in the analysis. The average age was forty six. The results are presented in table two.

Table 1. Pain Generators

Pain Origin	Patients
Chronic Pancreatitis	2
Para-scapular Pain Status Post Surgery	2
Post Surgical Knee Pain	1
Paravertebral Low Back Pain After Failed Surgery	14

Table 2. Trial Results

Disease: Pancreatitis	Implant: Painful area	Baseline Pain: (vas) 8/10 10/10	Post implant pain (vas): 4/10 0/10	
Average Parameters	Pulse Width: 254ms	Frequency: 50 hz	Intensity: 2.8 mA	Polarity: +00-
Disease: Shoulder Pain (para-scapular)	Implant: Painful Area	Baseline Pain: 10./10	Post Implant Pain: (vas) 10/10	
Disease: Lumbar Pain Status Post Surgery	Implant: Painful Area	Baseline Pain: 8.5/10	Post Implant Pain: 2.5/10	Pain Relief Range 100 to 70 percent
Average Parameters	Pulse Width: 280ms	Frequency: 53hz	Intensity: 3.0 mA	Polarity: +00-
Trial Success Rate	13/14			

Conclusion

The use of the subcutaneous modality to treat disease processes that are often thought to be recalcitrant to stimulation is encouraging. The procedure has minimal risks, is simple in its required technical skills, and is easy to access in regard to relief. The authors would recommend a multi-center prospective series to further evaluate this potentially helpful technique.

References

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Learning Objectives:

1. We have to think in this kind of stimulation when we can't use the spinal cord stimulation
2. Does stimulation work in nociceptive pain? Many of the cases we show are nociceptive pain, like it happens in abdominal pain
3. We need a multicenter study

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Sunday, December 9

1650-1657

Princesa Ballroom B-C (13)

3. *Electrode placement and relationships of periurethral nerves of an implantable electrostimulator, Accessa™, in female human cadavers.*

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Guangjian Wang, Ph.D., Kathy M. Ensrud-Bowlin, James L. Whiteside, M.D.

Introduction

Accessa Neuromuscular Stimulation Therapy (NMS™) is a technology for the treatment of urinary urge incontinence and other bladder dysfunction. NMS consists of an implanted periurethral electrode and a pulse generator. Although the exact mechanism is not known, the therapeutic effect is believed to be achieved by activating inhibitory reflexes to reduce undesired bladder contractions via the stimulation of afferent nerves.

Materials and Methods

In this study, we examined the periurethral electrode placement and its relation to nerve distribution in eight female human cadavers. Electrodes were inserted according to a standardized surgical protocol. Periurethral tissue including the vagina, bladder and supporting structures were next excised, fixed in formalin and processed for paraffin sectioning. Serial sections were stained with antibodies against S100/-PGP 9.5, -Substance P, -vesicular monoamine transporter and -nNOS to identify general, afferent, sympathetic and NOS efferent nerve fibers, respectively.

Results

Electrode contact sites were found located adjacent to the upper or middle thirds of the urethra. Transversely the electrodes were found within/lateral (n=4), within/posterolateral (n=9), and anterolateral (n=1) to the external urethral sphincter (EUS). The distance from the electrode in those locations to the EUS was 0.25 ± 0.5 , 2.9 ± 3.3 , and 1.0 ± 0.0 mm, respectively. The distance from the electrode to the urethra and vagina averaged 7.6 ± 3.4 mm and 8.8 ± 4.3 mm, respectively. Positive staining with all antibodies was found around the electrode with varying nerve densities depending on the electrode's location. Nerve densities were generally higher near the lumen of urethra and vagina wall than in the periurethral tissue parenchyma.

Conclusion

Placement of a permanent periurethral electrode in a female cadaver does interface the external urethral sphincter. The distribution of nerve fibers near the electrode is supportive of proposed neuromuscular therapeutic mechanisms.

References

Kenneth P. Roberts, Kathy M. Ensrud-Bowlin, Guangjian Wang, James L. Whiteside.

Acknowledgements

The protocol, study and manuscript have been developed with input from the authors and supported by American Medical Systems, Inc. USA.

Learning Objectives:

1. Electrode location in periurethral region
2. Identify nerve fiber distribution around electrode

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Sunday, December 9
1700-1707
Princesa Ballroom B-C (13)

4. An algorithm for peripheral neuromodulation in neuropathic pain

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Introduction

Several peripheral neuromodulation techniques show promise in the treatment of chronic neuropathic pain, such as external or percutaneous stimulation to nerves, to plexuses and even to the centre of non-dermatomal areas ('targeted'). Pain relief often lasts for days or weeks after a single episode of stimulation. Implanted stimulating devices deliver neuromodulation over an extended period of time but are expensive and risk complications, particularly infection, which might be avoided by intermittent self-administered external stimulation. No clinical features have been described to predict which option would provide most benefit and minimize risk for a particular individual.

We present an algorithm that we have devised in our institution in order to systematize decisions on peripheral neuromodulation therapies (Figure).

Materials and Methods

We undertook a retrospective casenote review of patients managed according to an algorithm in our tertiary-referral pain management clinic. Procedures were offered on a compassionate basis to patients reporting an unsatisfactory response to drug-based therapies.

Results

63 patients have been assessed using our algorithm. The pain problems were: 12 non-dermatomal pain, 10 chronic regional pain syndrome, 8 testicular, 6 cranial, 6 foot, 6 upper limb, 5 facial, 5 angina, 4 back pain, one genitofemoral pain. 36 gained good pain relief from external neuromodulation, and proceeded to learn how to administer this to themselves at home. 19 received implanted neuromodulation devices, and 5 more are awaiting temporary catheter trials with a view to this. 2 patients were lost to follow-up, and one had non-conclusive responses.

Conclusion

An algorithm permits appropriate peripheral neuromodulation procedures to be offered to patients with neuropathic pain. It selects patients who will benefit from self-administered external neuromodulation, and those who should be assessed for suitability for an implanted neurostimulator. It also prevents unnecessary implantation of a peripheral device in those who will respond to a less invasive approach.

References

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Acknowledgements

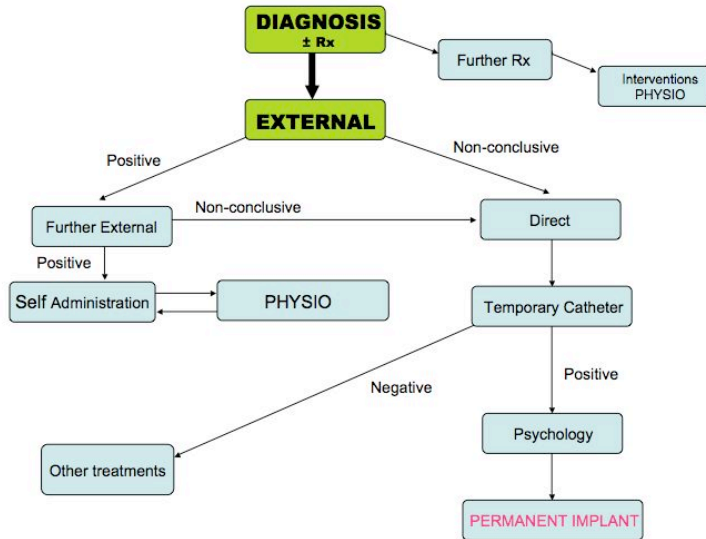
No external funding was sought or received for this work.



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Figure

Guy's & St Thomas' algorithm for neuromodulation in neuropathic pain



Learning Objectives:

To systematize the use of peripheral neuromodulation modalities in neuropathic pain treatment.

Sunday, December 9

1710-1717

Princesa Ballroom B-C (13)

5. Peripheral subcutaneous nerve stimulation

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Introduction

After the introduction of stimulation techniques for the treatment of chronic pain by means of SCS and PNS in the 70s, PNS-stimulation for treating Mononeuropathy, as well as sympathetic pain, underwent a renaissance. PNS techniques were introduced for treatment of CRPS I, occipital neuralgia, migraine, as well as neuropathies.

Materials and Methods

Following the convincing results, introduced by Barolat 2004, we performed a so-called "Field Nerve Stimulation" pilot study from May 2005 to February 2006 in 30 patients with different indications, mainly after FBSS. The **indication** was a well described exactly localized area of pain, partly connected to Allodynia. Leads were placed, allowing accessing the outer border of the area of pain. Eleven out of thirty-one Patients, who received an implantation of one to four leads (quadrode/octrode) and then underwent a one-week trial-phase, received an implantation of a complete system.

Results

Approximately 30% of the patients displayed a pain relief of more than 50% for a period of up to one year. 16 patients, who did not profit from peripheral nerve stimulation, were treated by SCS, according to our therapy scale. Since an adequate pain relief could not be achieved by SCS either, it can be assumed that simple subcutaneous stimulation can serve as a predictor for the success of spinal stimulation. In addition, patients who subsequently received an intrathecal opiate therapy showed significantly weaker results than other patients.

Conclusion

Peripheral nerve stimulation is a simple, promising method, with the best indication being a well localizable pain, and can be considered as the first step of invasive pain therapy for treating well-described pain emission. The operation technique is very simple and of low risk, however, long-term results have to be awaited.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

References

Teodor Goroszenuik, F.C.A., R.C.S.I., D.A., Sandesha Kothari, F.R.C.A., D.N.B., D.A., and Wolfgang Hamann, Ph.D., M.D., Reg Anesth Pain Med 2006;31:168-171.

Learning Objectives:

1. New Target in the therapy scale of chronic pain
2. Change of invasive pain algorithm

Sunday, December 9

1720-1727

Princesa Ballroom B-C (13)

6. Mechanical properties of electrode tips for spinal cord stimulation of two different companies

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Introduction

Occasionally, patients at whom electrodes were implanted for spinal cord stimulation, experience unpleasant sensations at sudden movements. The impression arose that this only occurred with electrodes of company ANS. We tested the mechanical properties of ANS electrodes in comparison with electrodes from Medtronic, which did not result in similar morbidity.

Materials and Methods

The Young's modulus of eight electrodes was established. Tested were 2 eight-points electrodes from ANS, 2 eight-points from Medtronic, 2 four-points from ANS and 2 four-points from Medtronic. The testing device was a low-load compression tester, equipped with a microbalance. All electrodes were tested four times.

Results

The Young's moduli of the four-points electrodes of ANS were 0,0063 and of the Medtronic one 0,0014. The Young's moduli of the eight-points electrodes of ANS were 0,0032 and of the Medtronic one 0,0060.

Conclusion

The results indicate that the 4-points electrodes from ANS were 4-5 times stiffer than similar electrodes from Medtronic. On the other hand, the 8-points electrodes from ANS were less stiff than those from Medtronic. Since the Young's moduli of the 4-points electrodes from ANS and the 8-points electrodes from Medtronic were in the same order of magnitude, it appears unlikely that the described morbidity was caused by differences in mechanical properties of the electrodes.

Learning Objectives:

1. Mechanical properties of spinal cord electrodes from different companies can differ to some extent, which may result in unwanted side-effects.
2. Companies sometimes modify electrodes without notifying their customers

Sunday, December 9

1540-1547

Marquesa III-IV (16)

1. Variability of spasticity in patients on intrathecal baclofen (ITB) and the use of the Personal Therapy Manager (PTM) to treat this variability of spasticity

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Introduction

Intrathecal baclofen infusion using implantable pumps is widely acknowledged to be clinically effective in the relief of intractable spasticity of either spinal or cerebral origin by reduction in muscle tone and spasms, and is generally well tolerated. With respect to the previous situation in our experience the majority of the

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

patients was satisfied. However careful inquiring showed that in a part of the patient population an optimal twenty-four hours' period could not be reached. We quantified in a limited amount of patients variations in spasticity and secondly tried to manage fluctuations by giving an additional bolus above the continuous intrathecal baclofen infusion (topping up bolus) using the recently developed PTM (patient therapy manager, Medtronic Minneapolis, USA).

Materials and Methods

Fourteen patients were asked to assess the occurrence of spasticity four daily periods using a VAS score for at least one month. In 8 patients a pilot study with the use of the PTM has been performed. For evaluation the Ashworth-, spasm- and clonus scale, the VAS score spasticity and the onset of the effect was measured with a stopwatch, the number of successful or unsuccessful activations as well as the side effects were monitored. The implantable pump was programmed without changing the baseline dose, the bolus was programmed as 5 %, and increased to 10% of the daily dose if the patient noticed no effect. For safety reasons the patient could only apply 4 boluses in 24 hours.

Results

The VAS scores for spasticity demonstrated a tremendous daily and intraday variation. The preliminary results of the application of the PTM device were promising. The latency of the topping up effects was 30 minutes. There were neither complications or side-effects. The majority of the patients need a 10% bolus for a clinical effect.

Conclusion

The clinical impression of frequent deviations in spasticity could be confirmed with the VAS-scores of spasticity. This indicates the need for a more optimal dose regimen. In larger controlled studies the preliminary benefits of PTM should be confirmed.

Acknowledgements

The study was performed with support of Medtronic Europe Sàrl, Tolochenaz, Switzerland

Learning Objectives:

- 1.Variations in spasticity
- 2.Usefulness of PTM
- 3.Safety of PTM

Sunday, December 9

1550-1557

Marquesa III-IV (16)

2. Novel Approach to Intrathecal Opioid Therapy for Chronic Nonmalignant Pain

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Introduction

The use of intrathecal opioids for acute and cancer pain is widely accepted. Their use in chronic nonmalignant pain is less clearly defined. Concerns with intrathecal opioid therapy include efficacy, tolerance, opioid-induced hyperalgesia (OIH) and side effects. Significant differences exist among pain practitioners regarding patient criteria, trial parameters, and the continued use of oral opioids. In a case study we describe an approach which has been successful in providing pain relief to patients while utilizing relatively low intrathecal doses of morphine without concurrent use of oral opioids.

Materials and Methods

The patient in this case study is an 84yo male with lumbar spinal stenosis who was not a surgical candidate. Patients were considered to be appropriate candidates for intrathecal therapy based on established practice criteria. PO opioids were discontinued over 6-8 weeks while adjuvant analgesics were continued. A three day trial in the university hospital with intrathecal morphine was performed. Patients were followed by the Chronic Pain and Physical Therapy services. Intrathecal morphine infusion was begun at 0.024mg/day and was increased to a maximum of 0.384mg/day at 12-14hr intervals.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Results

Initial pain rating of 10/10 with minimal activity was reduced to 6/10 after 12 hours. Incremental increases in dose resulted in resolution of pain (0/10) and improved functional activity (0.096mg/day) with no opioid-related side effects. At twelve months the intrathecal morphine dose has stabilized at 0.161mg/day with average pain rating of 4/10 with activity without PO opioids.

Conclusion

A low-dose intrathecal morphine protocol without requirement for concurrent PO opioid therapy to manage severe chronic pain in a patient with lumbar spinal stenosis is presented. CNS neural plasticity, opioid tolerance, OIH and opioid side effects are all likely to be of consequence with long-term intrathecal opioid therapy and may be lessened through use of protocols aimed at managing chronic nonmalignant pain with lower doses of opioids.

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Learning Objectives:

A low-dose intrathecal morphine protocol without requirement of concomitant administration of oral opioids has been described.

Sunday, December 9

1630-1637

Marquesa III-IV (16)

1. Successful ability to steer spinal cord stimulation current using single percutaneous lead, placed with "midline anchoring" technique.

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Introduction

There continues to be increasing interest in the ability to steer spinal cord stimulation (SCS) current. This has been shown only using a transverse tripole lead (1). We examined the possibility of steering SCS current along a single percutaneous lead, placed using a "midline anchoring" technique (2).

Materials and Methods

Ten patients with low back and/or lower extremity pain, scheduled for SCS trial, underwent insertion of a single Octrode (ANS) lead across the midline. No adjustments of lead position were made during the insertion. Areas of stimulation coverage were documented for each electrode, used as a cathode in a "guarded cathode" array. In the first three patients, additional testing was done by adding one additional cathode in either direction from the midline crossing electrode.

Results

All ten patients received excellent (>90%) coverage of their pain areas. Despite the wide variety of levels at which the midline contact was positioned, the use of it as cathode in a "guarded cathode" array produced bilateral back and/or leg coverage in all patients. Successful axial coverage was achieved in 70%, and was not related to the level of contact position. Steering of the current produced successful separation of right and left side stimulation in all subjects. Adding the extra cathode to the "guarded cathode" array allowed "smoother" movements of the current to achieve fine adjustments to the stimulation area. Contacts, positioned symmetrically to the midline, produced same area stimulation on the ipsilateral side, despite being separated by as much as 2 vertebral bodies distance.

Conclusion

"Midline anchoring" technique of a single, percutaneous Octrode allows fairly effective and structured steering of the current with bilateral or unilateral coverage. Position of the cathode, relative to midline, may play a more significant role in determining the area of stimulation than its position relative to a specific lower

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

thoracic vertebra.

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Learning Objectives:

1. Evaluate the ability to steer spinal cord stimulation current
2. Learn the benefits of across midline position of the lead
3. Review anatomy relevant to spinal cord stimulation

Sunday, December 9

1640-1647

Marquesa III-IV (16)

2. Can we identify microcirculatory parameters predictive of the outcome of spinal cord stimulation (SCS) in patients affected with non-reconstructable chronic critical leg ischaemia (CLI)?

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Dott. GD. Babbolin

Introduction

Aim of the study was to identify microcirculatory parameters predictive of the outcome of spinal cord stimulation (SCS) in patients affected with non-reconstructable chronic critical leg ischaemia (CLI). 1,2,3,4,5,6,7,8,9,10.

Materials and Methods

50 patients affected with non-reconstructable CLI were investigated by means of transcutaneous oxymetry and dynamic capillaroscopy before implantation of SCS (Octrode System®,Advanced Neuromodulation Systems [ANS],Plano,TX,USA)and after 1-month trial stimulation.

Results

Two groups of patients were identified, A and B, according to baseline TcPO₂-TcPCO₂ postural response. Group A showed: _TcPO₂ (depending-supine; mmHg) 18, _TcPCO₂ -14; group B: _TcPO₂ 8 and _TcPCO₂ -7. Dynamic capillaroscopy provided information about the nutritional flow, revealing the following before stimulation: in group A blood cell velocity (rCBV) 0,07 mm/sec, capillary density (CD) 14/mm², % open capillaries (%OC) 14,2%; in group B: rCBV 0,05 mm/sec, CD 9/mm², %OC 11%. After 1-month stimulation, a different improvement of transcutaneous oxymetry between the two groups was observed: in group A supine TcPO₂ 32,3 ± 6,8 (+70%) (mean _TcPO₂ 13); in group B supine TcPO₂ 17,3 ± 3 (+44%) (mean _TcPO₂ 5). Evidence of capillary recruitment after stimulation was provided by capillaroscopy: group A achieved a rCBV 0,18, CD 20, %OC 72%; group B showed a rCBV 0,09, CD 11, %OC 40%. Pain relief after stimulation was >50% in all patients, and after 12 months it turned out significant (p<0,005).

Conclusion

On the basis of our results and considering the complex microcirculatory reactivity, selection of patients should be based on more than one microcirculatory parameters. In our study a good outcome was associated with a postural _TcPO₂ >15 mmHg and also with an absolute value upon dependency ≥ 20 mmHg; thus, patients with a baseline supine TcPO₂ <10 mmHg, could also benefit from SCS, when showing an acceptable microcirculatory reserve capacity. So far, the above mentioned microcirculatory parameters allow for a good selection of patients which may enhance treatment effectiveness

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

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Learning Objectives

1. Could we identify clinical parameters different from the answer of the patient to prove efficacy of SCS?
2. Could the microcirculatory parameters be considered critical factors in the selection of SCS candidate among patients affected with non-reconstructable chronic critical leg ischaemia (CLI)?
3. Could we avoid unnecessary and expensive SCS trials basing patients selection on these parameters?

Sunday, December 9

1650-1657

Marquesa III-IV (16)

3. Effects of sacral surface electrical stimulation to the uterine dysfunctions.

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Takashi Murakami, MD, PhD, Kazunori Seki, MD, PhD, Yasunobu Handa, MD, PhD

Introduction

Previous studies have indicated that the electrical stimulation is effective for severe pain due to primary dysmenorrhea^[1]. However, no one has described the effect of electrical stimulation for dysmenorrhea on morphological and/or functional changes of the uterus. The purpose of this study is to clarify the uterine function changes during menstruation induced by sacral surface electrical stimulation (ssES) using static and cine mode MR imaging. Furthermore, we investigated the clinical effects of ssES to relieve symptoms of dysmenorrhea using by self-assessed visual analogue scale.

Materials and Methods

Subjects were healthy females and all of them were reproductive age. They had severe menstrual pain in every menstruation. We put the electrodes on the skin just above the posterior sacral foramina of the S2-4 and applied the cyclic electrical stimulation (3Hz or 30Hz) for 15 min to all subjects just in menstruation period (Day 1 or 2). Static T2-weighted FSE imaging (T2WI), cine mode T1-weighted SPGR imaging (T1cine) and cine mode T2-weighted HASTE imaging (T2cine) were performed by using 0.2T permanent and 1.5T super conducting magnet system before and after ssES. The morphological and functional changes were measured from these MR imaging. Furthermore, the self-assessed visual analogue scale (VAS) was performed to evaluate lower abdominal pain, lumbago, headache, nausea, appetite loss and fatigue before and after ssES.

Results

The muscle tension of the uterine smooth muscle was significantly decreased after ssES. Also, the peristaltic movement of the uterus in the subjects accompanied by severe menstrual pain became slow and weak significantly after ssES (Figure 1).

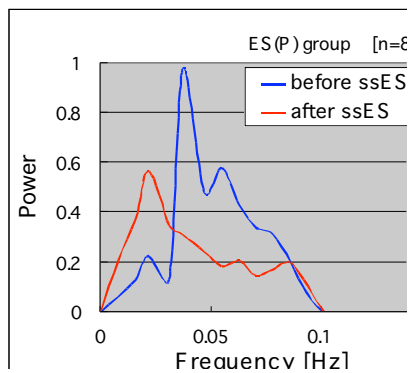
The VAS score of lower abdominal pain, lumbago and fatigue were significantly decreased after ssES (Figure 2). Furthermore, the score of appetite loss was significantly improved after ssES, although most of the subjects had no symptoms on headache and nausea.

Conclusion

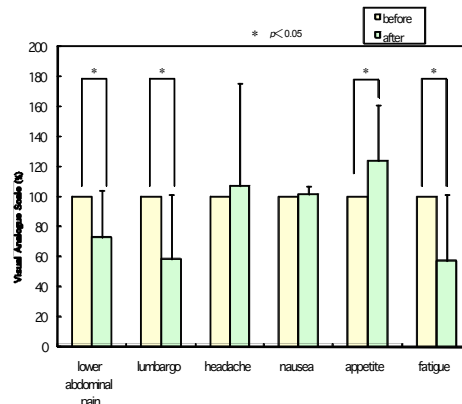
One of the possible explanations of clinical dysmenorrheal symptoms were improved by SsES, SsES might have the effects to decrease uterus contraction and to modulate the uterine dysfunction. SsES causes an inhibition of the parasympathetic pelvic neurons and/or a facilitation of the sympathetic hypogastric neurons in the spinal cord^[2] via electrically induced afferent volleys of the pudendal nerve.

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(Figure 1)



(Figure 2)

Figure and Table Legend

Figure 1 : Averaged power spectrum of uterine peristalsis before and after ssES.

Figure 2 : The mean normalized score of self-assessed visual analogue scale before and after SSES.

Learning Objectives:

1. To clarify the morphological and functional changes of the uterus during menstruation induced by sacral surface electrical stimulation in the healthy subjects with severe menstrual pain using MRI and MR cine technique.
2. To clarify the clinical effects of sacral surface electrical stimulation to relieve symptoms of dysmenorrheal using by self-assessed visual analogue scale.

Sunday, December 9

1700-1707

Marquesa III-IV (16)

4. Expectation and Treatment of Psychiatric Comorbidity in Chronic Pain Patients , With and Without Spinal Cord Stimulation

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

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Introduction

Despite an increase in the number of study in the last years, the level of evidence of the efficacy of Spinal Cord Stimulation (SCS) in chronic pain is "mediocre" (3; 5). Psychosocial dimension was considered as a risk factor for a good outcome of SCS devices but little consistency have reported in several studies (6; 2).

Materials and Methods

Before implant SCS device, chronic pain patients have screened by a multidisciplinary team. Intensity and dimensions of pain were assessed using the Italian Pain Questionnaire (1). A DSM-IV structured diagnostic interview (MINI) (4) was used to assess psychiatric disorders.

Results

Thirty-four patients have been implanted SCS devices (42.5%) of eighty consecutive chronic pain patients enrolled. Current psychiatric disorders was diagnosed in 25 patients with SCS (52.94%) and 24 without SCS (52.16%). Four patients with SCS (11.76%) and 11 without SCS (23.91%) assumed the psychiatric treatment at the follow up. The improvement of pain after six months was found in both groups, but pain relief $\geq 50\%$ resulted in 4 patients with SCS implant (11.76%) and in 7 without SCS implant (15.21%). Treatment of psychiatric comorbidity in pain relief $\geq 50\%$ patients was 1 for SCS implanted group versus six in the control group. Treatment of psychiatric disorders have a statistical relevance in the improvement of pain $\geq 50\%$ only in the group without SCS implant (ANOVA RM).

Conclusion

Poor compliance for psychiatric treatment is showed in this study, more in the SCS implanted than control group. Treatment of psychiatric comorbidity affects the relief of pain $\geq 50\%$ at 6 months. The expectation of analgesia only by SCS implant an not for treatment of psychiatric comorbidity also affects on the outcome of SCS implant devices.

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Learning Objectives:

1. expectation of SCS analgesia
2. the weight of psychiatric comorbidity in the management of patients with SCS device for pain
3. the influence of treatment of psychiatric comorbidity in the outcome of SCS therapy for pain

Sunday, December 9

1710-1717

Marquesa III-IV (16)

5. Neurogenic Mediated Intense Response of Psoriasis with Spinal Cord Stimulation Therapy

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Introduction

Spinal cord stimulation (SCS) is an effective treatment for patients with pain but the mechanisms of its action are inconclusive. Within a functional network of neurohormones, neuropeptides and cytokines¹, its not surprising that SCS increases blood flow^{2,3} or releases neuropeptides from sensory nerve endings⁴. We report a case where a patient treated with SCS for postlaminectomy syndrome with lumbar radiculopathy, experienced an intense flare-up of lower leg psoriasis.

Materials and Methods

A 44-year old female presented with postlaminectomy syndrome with lumbar radiculopathy. After months of conservative treatment (medication, nerve blocks, physical therapy and TENS), there was little reduction in pain. In for an SCS-trial, the patient was sterilely prepped and draped; the skin was anesthetized with 5cc of 2% lidocaine with epinephrine and 0.25% marcaine. A 14-gauge Tuohy needle was inserted and entered the epidural space at T12-L1. Separately, two 8-electrode leads (Advanced Bionics, Precision) were advanced up to T8, connected, programmed and stimulation covered the painful areas.

Results

With SCS-trial, pain score in the lower back and legs fell to 7 from highs of 10/10 but the underlying psoriasis was intensely aggravated. Skin on both lower legs became red and flakey with the patient feeling things crawling on her legs. The device was removed at day-7. Photographs at 2 days following lead removal show the skin was red and flakey but not as intense with the SCS turned on.

Conclusion

We showed that a preexisting condition of psoriasis was aggravated by SCS treatment. Others have shown that psoriasis resolves at sites of anesthesia, neuropeptides are up regulated and there is a proliferation of terminal cutaneous nerves^{5,6} and that arterioles can dilate further⁷. Since the mechanism of cutaneous neurogenic inflammation is associated with the release of neuropeptides from sensory endings^{5,8} and that SCS increases blood flow^{2,3}, its likely that SCS elicited the release of neuropeptides⁴ aggravating the psoriasis.

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Figure and Table Legend

Although an effective treatment for pain, SCS treatment has effects on the functional network of neurohormones, neuropeptides and cytokines. As shown here in this example of an underlying condition of

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

psoriasis, was aggravated by SCS treatment giving further insights into its mechanism of action. Use of pharmacological agents to counter the aggravation of psoriasis may be considered when SCS is indicated

Learning Objectives

Although an effective treatment for pain, SCS treatment has effects on the functional network of neurohormones, neuropeptides and cytokines. As shown here in this example of an underlying condition of psoriasis, was aggravated by SCS treatment giving further insights into its mechanism of action. Use of pharmacological agents to counter the aggravation of psoriasis may be considered when SCS is indicated

Sunday, December 9

1720-1727

Marquesa III-IV (16)

6. Inhibition of Histamine-induced Bronchoconstriction in Guinea Pigs by Pulsed Electrical Vagus Nerve Stimulation

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Steven Mendez, MS, BA

Introduction

Electrical stimulation of the vagus nerve has long been known to induce bronchoconstriction and increase pulmonary inflation pressure. Vagal nerve-induced bronchoconstriction is known to be mediated in part by histamine receptor activation of vagal nerve efferents. We believe that the component of histamine-mediated vagal nerve-induced bronchoconstriction can be significantly reduced by applying a specific pulsed electrical signal to the vagus nerve.

Materials and Methods

A well-established model of airway responses was used to measure pulmonary inflation, blood pressure and heart rate on anesthetized, paralyzed and ventilated male Hartley guinea pigs that were challenged with IV histamine to increase peak pulmonary inflation pressure (Ppi). In each animal, histamine challenges alone were alternated with histamine challenges while the specific pulsed electrical signal was applied to the left and right vagus nerves.

Results

Histamine challenges alone increased Ppi by an average of 3.04 +/-1.35 cmH₂O. Histamine challenges with the electrical signal applied to the vagus nerve increased Ppi by an average of 1.80 +/- 0.73 cmH₂O. The Ppi was reduced by an average of 1.24 cmH₂O (P=0.012; n=8). The specific electrical stimulation of the vagus nerve decreased the effect of IV histamine on Ppi by over 40%.

Conclusion

This study suggests that stimulation of the vagus nerve with the specific pulsed electrical signal can reduce bronchoconstriction caused by histamine, and may have clinical relevance in the treatment of pulmonary conditions like asthma and anaphylaxis.

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Acknowledgements



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

The following individuals also contributed greatly to the research: Charles Emala, M.D.; Hecheng Hu, M.D.; Puyun Guo, Ph.D. All research was funded by ElectroCore, LLC of Morris Plains, NJ

Learning Objectives:

1. Can an electrical signal applied to the vagus nerve reduce bronchoconstriction caused by histamine?
 2. What are the cardiac effects of such a signal?
-

Monday, December 10

0700-0707

Princesa Ballroom B-C (13)

1. Dual Device Therapy (Spinal Stimulation and Intrathecal Drug Delivery) for Treatment of Multi-Focal Pain

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Gurpreet Padda M.D., Richard Rauck M.D., John Barsa M.D

Introduction

A subset of patients require treatment with both spinal cord stimulators and intrathecal drug pumps. An FDA approved clinical study of a novel drug pump (Prometra™, InSet Technologies, Mt. Olive, NJ, USA) allows the prospective evaluation of this dual-therapy population. Patients with both spinal stimulators and intrathecal pumps may have better control of both their neuropathic and nociceptive pain than those with only one system.

Materials and Methods

The PUMP Study is a prospective, open-label study evaluating the accuracy, efficacy and safety of the Prometra pump system in treating pain. As of August 1, 2007, 69 patients have been enrolled in the PUMP Study. Of those, 10 (age: $49 \pm 9.4^*$, gender: 5F) have a concurrent stimulator at 4 clinical sites. Baseline data is collected pre-implant and follow-up is monthly for the first 6-months post-implant. Data collected includes adverse events, accuracy measure (returned morphine volume), pain scores (VAS, NRS, and ODI) as well as longitudinal intraspinal and systemic morphine dosing. Data is being tabulated by an independent third party (inVentiv clinical solutions, The Woodlands, TX).

Results

There have been no deaths or major morbidity. There has been one early catheter dislodgment requiring re-operation to correct. After a total of 605 device-days of follow-up, accuracy of drug delivery is $99.4\% \pm 2.4\%$. Programmed daily doses were $1.76 \pm 1.9 \text{ mg}^*$ (range: 0.28- 6.79 mg). VAS values show a 22.3% (NS) improvement, NRS values a 2.1 (NS) point improvement and ODI values a 24.6% ($p=.04$) improvement. *mean \pm standard deviation

Conclusion

Preliminary data indicate that dual-device therapy can be safely performed and improves patient outcomes. The Prometra pump has been shown to be accurate in this population. Future analyses will include a longitudinal analysis of opioid dosing correlated with catheter-tip location, pain-type as well as lead position.

References

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Acknowledgements

The PUMP Study is funded by InSet Technologies Incorporated, Mt. Olive, NJ, USA.

Learning Objectives

1. Spinal Morphine infusions in patients with previously implanted Spinal Stimulators
2. Introduction of a new programmable Spinal Infusion Pump

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Monday, December 10
0710-0717
Princesa Ballroom B-C (13)

2. A Randomized, Multidose, Double-blind Study to Evaluate the Analgesic Response and Safety of Ziconotide Intrathecal Bolus Injection in Patients With Severe Chronic Pain

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Introduction

Ziconotide is a nonopioid analgesic approved by the US Food and Drug Administration for the treatment of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatments such as systemic analgesics, adjunctive therapies, or intrathecal morphine. The efficacy and safety of ziconotide have been established using continuous intrathecal infusions, but no published studies have investigated ziconotide bolus administration.

Materials and Methods

In this double-blind, placebo-controlled study, each patient received four direct lumbar spinal injections that contained 0, 2, 4, or 8 mcg of ziconotide in a randomized sequence over a 1-month period. Data were obtained immediately before the injection (baseline) and hourly postinjection for 6 hours. The number of responders (ie, patients with a >30% or >50% reduction from baseline in Visual Analog Scale of Pain Intensity score) was calculated for each dose group. Safety evaluations included measurement of hemodynamic, respiratory, and neurologic parameters, as well as recording of adverse events.

Results

Six patients participated, yielding data for 24 injections. Responder results are summarized in Table 1. Patients who had a >50% reduction in pain score are also included in the >30% reduction group. Hemodynamic, respiratory, and neurologic measurements showed no significant changes from baseline with placebo or ziconotide. With the 8-mcg ziconotide bolus, two patients (33%) reported ataxia at 6 hours postinjection as well as nausea and vomiting with onset approximately 4 hours postinjection. Mild nausea and/or dizziness were reported after 33% of ziconotide boluses and 16% of placebo injections.

Reduction in Pain Score	Treatment			
	Placebo	2 mcg Ziconotide	4 mcg Ziconotide	8 mcg Ziconotide
>50%	0	1	1	3
>30%	1	1	2	4
<30%	5	5	4	2

Table 1. Pain Relief After Bolus Injection

Conclusion

Ziconotide bolus administration may allow for rapid assessment of intractable pain that is responsive to ziconotide, and bolus administration of ziconotide was well tolerated. Further research with larger sample sizes is warranted.

Acknowledgments

The support of Elan Pharmaceuticals, Inc., for this project is gratefully acknowledged.

Learning Objectives

1. Describe the analgesic response to bolus administration of ziconotide
2. Recognize the adverse events associated with bolus administration of ziconotide
3. Understand the implications for future research regarding bolus administration of ziconotide and long-term intrathecal infusion of ziconotide

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Monday December 10
0720-0727
Princesa Ballroom B-C (13)

3. A Spiral Electrode for Peripheral Nerve Stimulation

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Chong Lee, M.D.

Introduction

Peripheral nerve stimulation has both theoretical and practical advantages over spinal cord stimulation. Although Medtronic once made cuff electrodes for peripheral nerve stimulation, their manufacture was discontinued for both economic and biologic reasons. Cuff electrodes applied too tightly to the nerve created new nerve damage and it was impossible to direct the stimulation to those fibers innervating the painful area within the territory of a nerve. Furthermore, inappropriate positioning of the electrode and lead wire could lead to angulation of the cuff and nerve compression. When the cuff electrode was abandoned, surgeons tried to adapt spinal cord electrodes to stimulate peripheral nerves. Some have used PISCES electrodes, others used paddle electrodes sewn together at one edge to create a V trough for the nerve, others tried to lie the nerve on a paddle electrode, etc. None of these improvisations has been satisfactory. Medtronic does not manufacture an electrode for peripheral nerve stimulation.

Materials and Methods

The spiral electrode we have designed solves some of the electrode-nerve interface problems and does not appear to damage the nerve in any way. It is easy to apply and to remove, if necessary. However, the diameter of the helix is a critical feature. Our electrode was designed for the sciatic nerve and is too large for the nerves of the arm. It will be necessary to have several sizes of helix to properly utilize this design concept for peripheral nerve stimulation. It is not known if more than four contacts will improve outcomes.

Results

The results in our series of 18 patients will be presented. Fourteen of 18 patients implanted had partial or complete relief of pain.

Conclusion

Peripheral nerve stimulation requires the development of electrodes designed for this purpose and appropriately sized for the nerve to be stimulated.

Learning Objectives:

1. Understand peripheral nerve stimulation for pain relief.
2. Understand electrode design issues for peripheral nerve stimulation.

Monday December 10
0730-0737
Princesa Ballroom B-C (13)

4. Motor Cortex Stimulation for Intractable Chronic Pain

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Introduction



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Motor Cortex Stimulation (MCS) is currently considered an acceptable safe, and effective treatment for patients with intractable chronic neuropathic pain conditions. We report our initial results with 31 MCS patients.

Materials and Methods

All patients who underwent MCS from 1998 - 2006 were reviewed. All patients suffered from intractable chronic pain that was refractory to medical therapy. All patients were evaluated by a pain psychologist and were deemed acceptable candidates for implantable pain therapy. MCS was performed in two stages: 1) for a minimum of one week an epidural electrode was implanted over the motor region corresponding to the pain topography; 2) patients who were judged to derive significant reduction in pain were implanted with an internal pulse generator for long-term stimulation in a second stage procedure. Pre- and post operative visual analog pain scores (VAPS) were recorded in all patients. Patients were also asked to estimate the percent pain reduction derived from the procedure.

Results

Individual pain diagnoses as follows: trigeminal neuropathic/deafferentation pain (n=22); post-stroke pain (n= 7); post-herpetic neuralgia (n=1), and phantom limb pain (n=1). The average duration of symptoms was 5 years; mean follow-up after surgery was 1 year. For all 31 patients, the mean pre- and post-VAPS were 8.3 and 4.3 respectively. The average subjective pain reduction was 41%. For the 22 patients with facial pain, mean pre and post-operative VAPS were 9.0 and 3.8, respectively (p=0.01). For patients with post-stroke pain, VAPS scores were reduced from 9.0 to 6.0 (p > 0.05). Of the 22 patients who had a successful trial and received a permanent implant, the average VAPS at the most recent follow-up was 4.3, providing those patients with an estimated pain reduction of 50%. Three patients had an isolated seizure during IPG programming. Otherwise there were no significant complications.

Conclusion

MCS provides significant pain relief for patients with intractable trigeminal neuropathic/deafferentation pain and to a lesser for those with post-stroke pain.

Learning Objectives:

Understand the pain conditions that respond to motor cortex stimulation

Monday December 10

0740-0747

Princesa Ballroom B-C (13)

5. Spinal Cord Stimulation with Interleaved Pulses: A Randomized, Controlled Trial

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Introduction

The development of multi-contact spinal cord stimulation electrodes and programmable, implanted pulse generators has increased the likelihood of achieving and maintaining pain/paresthesia overlap. This study sought to determine if delivering interleaved stimulation pulses (rapidly interleaved pulse trains using two different contact combinations) and/or doubling frequency would improve overlap in patients with failed back surgery syndrome.

Methods

Using a patient-interactive computer system that quantifies pain/paresthesia overlap and presents various stimulation settings in randomized, double-blind fashion, we compared the effect on overlap of interleaved stimulation versus standard treatment with a single contact combination, controlling for frequency doubling. The interleaved pulses were generated by using the computer system to gate the pulses of a single-channel generator, emulating multichannel stimulation by adjusting the interpulse interval to the smallest possible value of 0.66 milliseconds. Amplitude (charge per phase, determined by varying pulse voltage or width) was maintained at a subjectively comfortable intensity for all trials. Additional variables were the number of percutaneous electrodes used (one or two) and the phase angle between interleaved pulses. At our default 60 pulses per second ("low frequency"), each 360° interpulse interval occurs in 16.7 milliseconds; therefore, 0.66 milliseconds approximates a phase angle of 14°. We studied the effect of stimulation with phase angles from 14 to 346°.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Results

Multivariate analysis of 266 test results from 15 patients revealed a statistically significant ($p \leq 0.05$) association between increased computer-calculated pain/paresthesia overlap and 1) high and low frequency interleaved stimulation using two contact combinations and 2) frequency doubling using one combination. We found no significant effect for electrode configuration (single or dual), pulse width matching, or phase angle.

Conclusions

The statistically significant advantages we observed for interleaved stimulation are explained, in part, by the effects of frequency doubling and have important implications for the design and adjustment of pulse generators.

Acknowledgements: The Johns Hopkins University received support for this study from Medtronic, Inc.

Figure Legends:

Figure 1. For each test, the patient adjusted amplitude, drew the area of paresthesia, and rated pain/paresthesia overlap. The computer then calculated overlap, and the patient let stimulation subside before the next test.

Figure 2. Waveforms produced by interleaved stimulation of contact combinations "A" and "B" on a 4-contact electrode (scale exaggerated) with no contact used twice. In this example, the pulses in A lead and lag those in B by the same interval (a 180° phase angle).

Figure 3. Avoiding use of the same contacts for combinations A and B allowed us to deliver standard stimulation simultaneously to all contacts used in either combination. With the single channel output connected to cathodal and anodal poles on the pulse generator common to both, voltage and pulse width are necessarily the same. (Right) Simultaneous delivery of different pulse amplitudes and/or widths to different contact combinations would require a true multichannel stimulator and is beyond the scope of this study.

Figure 4. (Top) Stimulation with contact combination "A," results in an area of paresthesia (A) and an area of sub-threshold stimulation (a). (Bottom) Rapid, interleaved stimulation, A+A, which is comparable to frequency doubling, expands the area of paresthesia A+A to include area a+a and, thus, also expands the area of sub-threshold stimulation to a+a.

Figure 5. The effects of interleaving two pulse trains are non-linear and significantly more than the sum of the parts. Is the expansion confined to the intersection A+B, which is exposed to frequency doubling, or does A itself expand with the addition of B, and vice versa? Each area of paresthesia is surrounded by an area of sub-threshold stimulation "a" and "b." If the perception threshold is exceeded at the intersection of a+b, the area of paresthesia will increase.

Learning Objectives:

Understand the impact on SCS-generated pain/paresthesia overlap of 1) low frequency, rapidly interleaved stimulation of two different contact combinations on one or two electrodes, 2) doubling the stimulation frequency using one contact combination, 3) electrode configuration (one or two electrodes), 4) pulse width matching of amplitudes, and 5) phase angle.

Monday, December 10

0750-0757

Princesa Ballroom B-C (13)

6. Cranial Peripheral Nerve Stimulation for Intractable Headache: Prospective Two Year Followup Results

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Introduction

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Chronic stimulation of the occipital nerve(s) is reportedly effective in the treatment of medically intractable headache and pain involving the posterior head and neck. Many patients present with head pain outside this distribution involving the frontal and/or temporoparietal regions. We have prospectively evaluated the effect of chronic stimulation of those nerves whose sensory distribution parallels that of patient's head pain with a minimum followup of 2 years.

Materials and Methods

35 patients have been treated in this protocol; 30 have complete 2 year followup data. Stimulation was performed of one or all of the following nerves depending upon the semiology of the patient's head pain: greater and lesser occipital, supraorbital, infratrochlear and auriculotemporal nerves. Trial stimulation was performed for 3 to 4 days and if successful, a permanent stimulation system consisting of one and four leads and pulse generator were implanted. Followup data was obtained for a minimum of two years on all patients.

Results

One of the 35 patients failed to obtain sufficient relief during trial stimulation to warrant permanent implantation (3%). 26 of 30 implanted patients obtained good to excellent pain relief (87%). Three patients failed to obtain lasting relief and ultimately had the device removed (10%). Seven of 30 patients underwent one or more reoperations due to hardware failure or electrode migration (23%); this failure rate has fallen significantly with new fixation techniques and with the use of stronger lead constructs. Complications include two episodes of electrode erosion through the skin (7%) and one infection (3%) related to this erosion.

Conclusion

Chronic stimulation of the cranial peripheral nerves whose sensory distribution parallels the semiology of patient's head pain appears to be a low risk and highly effective treatment for medically intractable headache and head pain.

Learning Objectives:

1. Participant will become aware of the potential treatment of chronic headaches with neuromodulation
2. Participant will understand the potential efficacy of treatment of chronic headaches with neuromodulation
3. Participant will become aware of the risks and complications of treatment of chronic headaches with neuromodulation

Monday, December 10

1630-1637

Princesa Ballroom B-C (13)

1. Spinal Cord Stimulation indications and outcomes: A retrospective review.

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Introduction:

The majority of the data regarding spinal cord stimulation (SCS) indications and outcomes are collected at academic institutions where the evaluations and procedures are performed by a variety of physicians with various levels of training and expertise.(1-9) Such pooled data may not be representative of outcomes at any one physician's practice. Here, we present SCS outcomes for a single physician over a 2.5 year period.

Materials and Methods:

Fifty-eight patients underwent a percutaneous trial of spinal cord stimulation; 30 (51%) went on to implantation. Implantation criteria included a better than 50% reduction in pain complaints during the spinal cord stimulation trial. Patients were instructed to track activities during the trial period and were required to show a meaningful improvement in addition to reporting reduction in overall pain. Patient demographics

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

	Male	Female	Total
Number of patients	29	29	58
Number of implants	12	18	30
Mean follow for implants(days)			435
Median follow up for implants(days)			360

Results:

The majority of failed trials were in patients with principal complaints of axial lumbar pain; excluding these, the trial-to-permanent ratio was 25/39 (64%). Considering a minimum of six months follow-up after permanent implantation, pain control ranged from a low of 30% improvement to a high of over 90%. These results have been sustained.

Stimulator Trial/Implant by Disease Condition

Disease process	Male Trial(Implant)	Female Trial(Implant)	Total Trial(Implant)%
Primary lumbar axial pain	17(5)	2(0)	19(5)/26%
Primary radicular pain Cervical	2(1)	1(0)	3(1)/33%
Primary Radicular pain Lumbar	5(4)	16(11)	21(15)/71%
CRPS Upper extremity	1(0)	6(5)	7(5)/71%
CRPS lower extremity	4(2)	4(2)	8(4)/50%
All pain complaints	29(12)	29(18)	58(30)/52%
All pain complaints excluding axial	12(7)	27(18)	39(25)/64%

Intervention	Male	Female	Total
Revision of displaced leads		0	0
Placement of retrograde lead		1	1
Explantation for infection	1	1	2
Explantation for loss of efficacy		2	2
Reimplantation following explant		1	1
Revision IPG		1	1
[AF1] All interventions			7

Four patients underwent explantation; two for lack of efficacy over time and two for infections. One patient with infection opted to have reimplantation when they had healed and is currently doing well.

Intervention	Male	Female	Total
Revision of displaced leads		0	0
Placement of retrograde lead		1	1
Explantation for infection	1	1	2
Explantation for loss of efficacy		2	2
Reimplantation following explant		1	1
Revision IPG		1	1
All interventions			7

Of interest, no patient had an infection associated with primary implantation; infection occurred only following revision and only at the IPG site. Two additional patients underwent revisions for replacement of faulty or depleted IPG's, or to place retrograde leads to improve stimulation coverage. No patients required revision for displaced antegrade leads at any time in the period under review.

Conclusion:

This study adds to the body of evidence that spinal cord stimulation is effective in the management of a variety of painful conditions and has relatively low rates of complication over time.

References:

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

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Figure and Table Legend:

Table 1: Breakdown by demographics and procedure performed.

Table 2: Breakdown by complications.

Table 3: Breakdown by disease process.

Learning Objectives:

1. To describe typical clinical experiences with SCS
2. To report observed complication rates
3. To show sustained pain relief with SCS

Monday, December 10

1640-1647

Princesa Ballroom B-C (13)

2. Spinal Cord Stimulation for Intractable Pelvic Pain. Case Report.

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Dr Paul Murphy, MD, MRCPI, FCARCSI, FFPANZCA, Dr Abdul AIMajadi MB, FCARCSI, Dr Aamir Zuberi MB, FCARCSI

Introduction: Pubic symphysis disruption may occur as a result of trauma or in labour particularly in the setting of breech presentations and cephalo-pelvic disproportion. We report the case of a 39 year old female who presented with a five-year history of chronic pelvic pain following spontaneous pubic symphysis disruption in childbirth. Surgical fixation provided a maximum of 20% pain relief. Medications were ineffective. Bilateral percutaneous octode spinal cord stimulator electrodes (Advanced Bionics, Valencia, US) were implanted.

Materials and Methods: Case report and literature review.

Results: Stimulation at the T10 level was associated with complete resolution of pain. The patient has discontinued all medications and has returned to full time employment.

Conclusion: Spinal cord stimulation is an effective treatment for chronic intractable visceral pelvic pain post pubic symphysis disruption.

References: 1. Kapural L, Narouze SN, Janicki TI, Mekhail N. Spinal cord stimulation is an effective treatment for the chronic intractable visceral pelvic pain. Pain Med 2006 Sep-Oct;7(5):440-3.

Learning Objectives:

1. Spinal cord stimulation should be considered as a potentially useful modality in the management of chronic intractable visceral pelvic pain secondary to pubic symphysis disruption.

Monday, December 10

1650-1657

Princesa Ballroom B-C (13)

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

3. Peripheral Nerve Field Stimulation: A novel treatment in chronic low back pain and failed back surgery syndrome.

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Dr Bruce Mitchell (M.D), Dr David Vivian (M.D), and Dr Chantelle Sinclair (PhD)

Introduction

Chronic low back pain that has failed to respond to traditional treatment methods is historically difficult to manage. The aim of this study was to evaluate the usefulness of peripheral nerve field stimulation as a treatment option for patients with chronic low back pain.

Materials and Methods

Over a 12 month period we collected data on 14 consecutive patients who had a successful trial and were subsequently implanted with octrode, percutaneous leads placed subcutaneously within the major area of pain in the low back or trunk. Eleven patients met the diagnostic criteria for failed back surgery syndrome. A questionnaire was used to assess outcomes including: pain indices, post-operative changes in analgesic use and the overall level of patient satisfaction. The response rate was 93% (13/14). The average follow-up time was 7 months.

Results

There was a statistically significant decrease in pain levels: an average reduction of 3.77 on the visual analogue scale. Two patients reported a poor response to all outcome measures. The remaining eleven reported successful outcomes and an average pain reduction of 4 on the visual analogue scale. The majority of patients reported a decrease in analgesic use after peripheral nerve field stimulation. Pain relief was significantly and highly correlated with reduced analgesic intake and patient satisfaction. No adverse events or complications were reported.

Conclusion

This pilot study demonstrates a potential treatment option that is safe, reversible and effective for patients with chronic low back pain that have exhausted other treatment options.

Monday, December 10

1700-1707

Princesa Ballroom B-C (13)

4. Method of Uni-acupoint Electrical Stimulation and Application in Pain Control

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Chuansen Niu, Luming Li

Introduction

Many animal and clinical researches have shown that Electroacupuncture (EA) is effective to control pain and drug abuse. However the regular method is bi-acupoint stimulation, thus the current will pass different meridians and acupoints, confusing the effects of single acupoint. So we have developed a uni-acupoint electrical stimulator including pulse generator and electrodes, and used it in rat experiments to control pain.

Materials and Methods

Female Wistar rats were in three groups, i.e. control, bi-acupoint stimulation and uni-acupoint stimulation. The pain threshold was measured by tail flick latency (TFL). The stimulation parameters were: Amplitude of 0.8-1.0-1.2mA, rate of 2Hz, pulse width of 600_s. Bi-acupoint stimulation was applied by two needles inserted in left and right Zusanli. As for uni-acupoint stimulation, a stainless steel foil in ring shape with O.D. of 8mm and I.D. of 2mm was mounted on the left leg acting as an electrode, and a needle was inserted in Zusanli through the hole of ring electrode acting as the other electrode, in which the needle was insulated by Teflon coating except for stimulating distal end and proximal connector.

Results

Bi-acupoint stimulation induced an increase in TFL of 21.3% during EA therapy and 15.6% post-EA, and the figures for uni-acupoint stimulation were 16.6% and 13.1%. The effect of uni-acupoint stimulation is not as

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

good as bi-acupoint stimulation, suggesting that the effects of EA may be induced by not only the stimulated acupoint but also the involved meridians and acupoints in the path of stimulation current.

Conclusion

The novel therapy of uni-acupoint electrical stimulation is capable of effectively increasing TFL and controlling pain. The therapy is also a simple method, showing easier operation and slighter injury, and makes it possible to develop an integrated electrode module mounted on single acupoint, and further an implantable micro-acupoint-stimulator powered by the pulse generator outside the body may be an interesting idea.

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Acknowledgements

This study has been supported by National High Technology R&D Program of China (863 program) (Grant No.2006AA02Z4E9) and National Key Technology R&D Program of China (Grant No.2006BAI03A18).

Learning Objectives:

1. Uni-acupoint EA is a novel method for acupoint electrical stimulation.
2. Uni-acupoint EA is effective to control pain in rats.
3. Uni-acupoint stimulation may lead to novel implantable stimulator.

Monday, December 10

1710-1717

Princesa Ballroom B-C (13)

5. Identification of the Location of the Dorsal Genital Nerves with Subsequent Electrical Stimulation for Treatment of Overactive Bladder Symptoms in Women

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Introduction: To (1) identify the course and (2) test stimulation of the dorsal genital nerves for treatment of overactive bladder in women.

Materials and Methods: 6 human female cadavers were dissected to trace the course of the dorsal genital nerves from the glans clitoris distally to the deep pelvis proximally. Once the course was identified a site along the nerves at the base of the clitoris between the corporal bodies and the pubis was chosen for electrical stimulation in adult women with overactive bladder. After lead placement a 7 day trial period comparing pre-stimulation voiding parameters with those recorded during the 7 day period of active stimulation was performed.

Results: (1) The dorsal genital nerves pierced the perineal membrane 2.7 cm lateral to the external urethral meatus, traveled along the bulbospongiosus muscle posterior to the crura and then hooked over from medial to lateral to run on the antero-lateral surface of the body of the clitoris (see figure). (2) Temporary leads were implanted in 21 women. Percutaneous electrode placement required 5 to 10 minutes and was well tolerated. Pad weight was reduced by $\geq 50\%$ in 13 of 17 subjects (76%) (4 did not complete 24 hour pad testing) and 47% of subjects reported $\geq 50\%$ reduction in incontinence episodes. Of the subjects who reported severe urgency at baseline, 81% experienced a 50% or greater improvement.

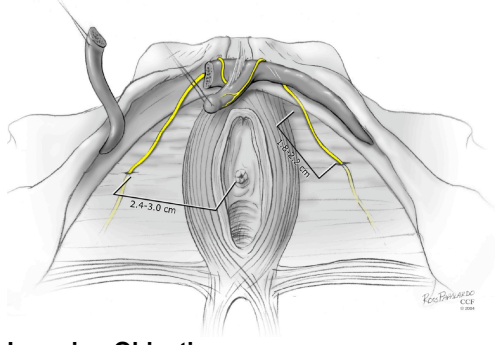
Conclusion: This study demonstrated a consistent course of the dorsal genital nerves in relation to the clitoris and identified a location conducive to neuromodulation. Electrodes to stimulate the dorsal genital nerves can be placed percutaneously and a home testing period showed a reduction in overactive bladder symptoms with dorsal genital nerve stimulation.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Acknowledgements

This work was supported by The State of Ohio BRTT03-10, NIH HD40298 and NDI Medical

Figure and Table Legend – Course of dorsal genital nerves in the female



Learning Objectives:

1. Recognize the anatomical course of the female dorsal genital nerves
2. Understand the rationale for lead placement at this site
3. Recognize the results of neuromodulation of the dorsal genital nerves for the treatment of overactive bladder in women

Monday, December 10

1720-1727

Princesa Ballroom B-C (13)

6. Automated vs. Manual Spinal Cord Stimulator Adjustment:

A Sensitivity Analysis of Lifetime Cost Data from a Randomized, Controlled Trial

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Introduction

Results of a randomized controlled trial (RCT)¹ comparing manual with automated² computerized adjustment of spinal cord stimulation (SCS) parameters in patients with “totally implanted” power generators revealed that the automated method allowed patients to test more settings in a given time, achieve significantly more paresthesia/pain overlap, and increase battery life. In that study population, we previously reported that the lifetime per patient cost reduction achieved with automated adjustment is \$303,756 (95% CI = \$116,503-491,009). In the current study, we analyzed the sensitivity of this cost savings to usage time/day, inflation rate, discount rate, and years of use.

Methods

We used a standard spreadsheet method with a suitably adjusted standard equation to analyze the cost sensitivity of the RCT data.

Results

Regardless of hours/day of use (Table 1), inflation (Table 2), discount rate (Table 3), or years of use (Table 4), SCS remains significantly less expensive with automated versus manual adjustment of stimulating parameters. This cost savings is attributable to increased battery life.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Conclusions

Computerized, patient-directed parameter adjustment significantly improves the cost effectiveness of SCS as a therapy for chronic pain. Sensitivity analyses reveal that the cost savings is robust across a representative range of parameters. These results indicate that power generators with rechargeable batteries should also increase the cost effectiveness of SCS, assuming they increase battery life as expected.

Table 1. The impact of hours/day of stimulation on mean lifetime cost associated with use of manual versus automated spinal cord stimulator parameter adjustment.

Hours/Day	\$ Manual	\$ Automated	\$ Cost-Savings	\$ 95% CI
18	685,186 ± 801,139	456,151 ± 481,531	229,035	87,911 to 370,158
12	459,070 ± 534,270	308,174 ± 321,365	150,895	57,197 to 244,594

Table 2. The impact of inflation rate on mean lifetime cost associated with use of automated versus manual spinal cord stimulator parameter adjustment.

% Inflation Rate	\$ Manual	\$ Automated	\$ Cost-Savings	\$ 95% CI
0	580,826 ± 672,521	385,589 ± 17,988	195,237	75,162 to 315,313
6	1,531,460 ± 1,834,393	1,025,782 ± 1,136,415	505,678	193,759 to 817,597
8	2,266,487 ± 2,746,255	1,530,205 ± 1,741,880	736,282	282,487 to 1,190,076
10	3,463,055 ± 4,246,210	2,362,566 ± 2,766,643	1,100,489	423,215 to 1,777,746

Table 3. Impact of the discount rate on mean lifetime cost associated with use of automated versus manual spinal cord stimulator parameter adjustment.

% Discount Rate	\$ Manual	\$ Automated	\$ Cost-Savings	\$ 95% CI
0	1,557,596 ± 1,866,655	1,043,603 ± 157,534	513,993	196,950 to 831,036
6	587,579 ± 680,669	390,067 ± 402,968	197,512	76,028 to 318,996
8	462,652 ± 530,294	307,434 ± 311,686	155,218	59,915 to 250,522

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

10	376,764 ± 427,434	250,897 ± 250,044	125,867	48,705 to 203,028
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Table 4. Impact of time on mean lifetime cost associated with use of automated versus manual spinal cord stimulator parameter adjustment.

Years	\$ Manual	\$ Automated	\$ Cost-Savings	\$ 95% CI
2	67,395 ± 66,811	48,849 ± 39,029	18,547	6,157 to 30,936
5	151,884 ± 161,943	103,058 ± 95,929	48,826	19,516 to 78,135
10	291,558 ± 320,394	195,360 ± 188,016	96,198	38,342 to 154,053
20	570,419 ± 636,301	378,500 ± 370,934	191,919	76,212 to 307,625
35	923,512 ± 1,071,975	650,523 ± 646,337	272,988	47,373 to 498,604
50	1,400,407 ± 1,587,421	921,081 ± 923,715	479,326	190,846 to 767,806

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Acknowledgements

This research study was supported by Stimsoft, Inc.

Learning Objectives

1. Understand the impact of SCS duration of use variables and of economic variables on mean lifetime cost of SCS with automated versus manual adjustment of the spinal cord stimulator.
2. Understand the impact of battery life on cost effectiveness of SCS.

Monday, December 10
1520-1527
Marquesa III-IV (16)



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

1. Ultrasound-guided placement of a permanent percutaneous femoral nerve stimulator leads for the treatment of intractable femoral neuropathy

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Introduction

Femoral nerve injury is a rare complication of cardiac catheterization with a reported incidence of 0.21%. It is usually caused by direct trauma during femoral artery access, compression from a hematoma or because of prolonged digital pressure for post-procedural hemostasis [1].

We are reporting a novel approach for femoral nerve electric stimulations for the treatment of intractable femoral neuropathy using a percutaneous approach with real-time ultrasound imaging to non-invasively identify the nerve and avoid vascular injury which was the initial cause of the femoral neuropathy.

Case Report

We report on a 61-year-old male who developed a right groin hematoma after cardiac catheterization for chest pain evaluation 18 months before presentation. Subsequently, he developed sharp stabbing pains in the right groin and the anterior aspect of the thigh radiating down the medial aspect of the leg to the big toe. Electromyography (EMG) and nerve conduction studies confirmed the diagnosis of right femoral nerve neuropathy.

Patient neurological examination showed weakness of the right quadriceps muscle, decreased patellar reflex, and decreased touch sensation and paresthesias along the distribution of the saphenous nerve. He failed multiple treatment modalities (tricyclic antidepressants, different membrane stabilizers, NSAIDs, narcotics, topical agents, PT, TENS, acupuncture) and continued to complain of severe neuropathic pains that markedly interfere with his daily activities. After appropriate psychological evaluation, we elected to proceed with a trial of peripheral nerve stimulation.

A curved array ultrasound probe 2-5 MHz (HD11- XL, Philips) was used to identify the femoral nerve and vessels. Two percutaneous octad leads (Medtronic, Minneapolis, MN) were placed under real-time sonography and the placement was double checked with fluoroscopy (Fig 1-3).

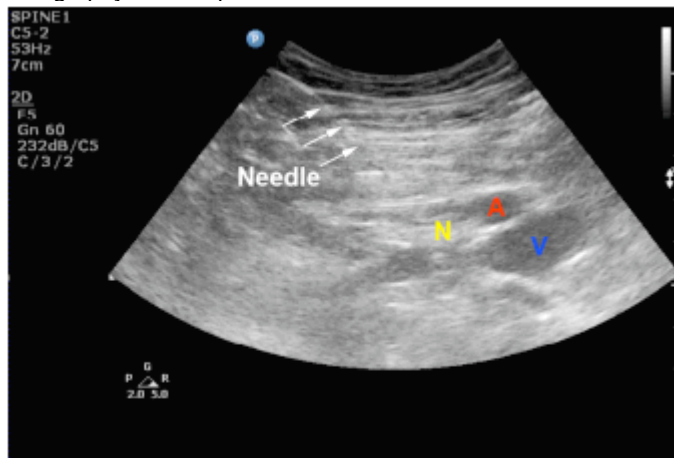


Figure (1):

Short axis image with the needle (arrows) out-of-plane in order to pass the lead longitudinally. V, femoral vein. A, femoral artery. N, femoral nerve.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

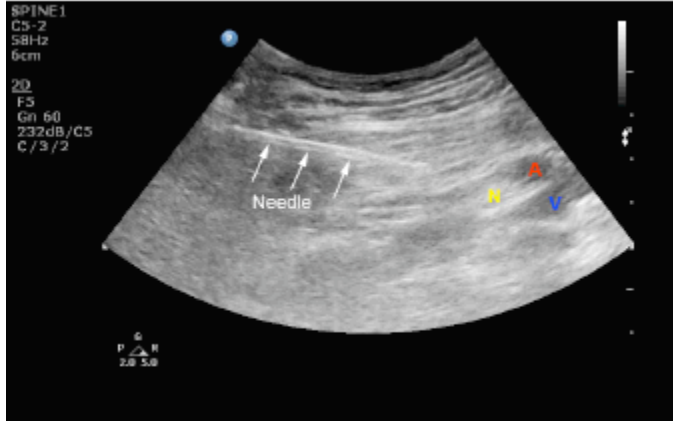


Figure (2):

Short axis image with the needle (arrows) in-plane in order to pass the lead across the nerve. V, femoral vein. A, femoral artery. N, femoral nerve.

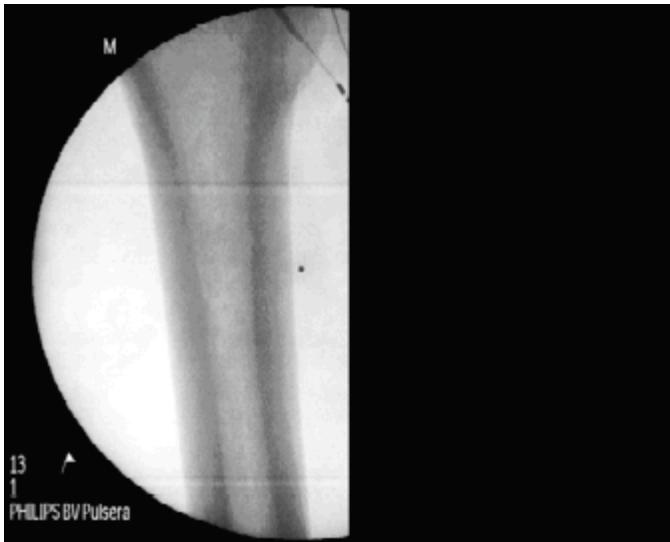


Figure (3):

AP view showing both leads. A: regular octade lead (longitudinal). B: compact octade lead (horizontal).

One lead was placed along the longitudinal axis of the nerve and the patient had good coverage over the anterior thigh areas but not below the knee. So another lead was placed horizontally across the femoral nerve to be able to stimulate all the branches and the patient reported good coverage along the saphenous distribution down to the foot. The patient then underwent a permanent implant after a successful trial for 7 days with the subcutaneous implant of a rechargeable generator (Restore®, Medtronic, Minneapolis, MN) in the right lower quadrant of the abdomen. The patient continues to be pain free 6 months after the implant and he managed to off all his pain medications.

Discussion

Peripheral nerve stimulation has been used to treat different pain syndromes in the upper and lower extremities with variable success and it usually requires an open surgical approach [2-3].

Here we described a percutaneous approach for femoral nerve stimulation with ultrasound guidance which allowed precise placement of the stimulating lead very close to the femoral nerve without the need for surgical exploration.

References

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

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Acknowledgements

Funding was solely provided by institutional and/or departmental resources.

Learning Objectives:

1. To emphasize the role of peripheral nerve stimulation in the management of neuropathic pain syndromes.
2. To discuss percutaneous versus surgical approaches to neuromodulation.
3. To identify ultrasound imaging as a new tool in the arena of neuromodulation.

Monday, December 10

1530-1537

Marquesa III-IV (16)

2. A controlled comparative cadaveric investigation of percutaneous spinal cord lead anchoring

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Introduction

Maintenance of paraesthesia with spinal cord stimulation remains a problem due to lead migration. We have undertaken a controlled comparative *in vitro* investigation of the commoner anchor designs.

Materials and Methods

Four operators of varying experience undertook lead placement and anchoring of percutaneous spinal cord stimulator leads in cadaveric specimens using instrument tied square knots. 34 lead anchorings were undertaken in total. Short silastic tapered suture sleeve (SC-4305) (Advanced Bionics) (n= 8) ; long silastic anchor (SC-4310) (Advanced Bionics) (n= 7), (1106) (Advanced Neuromodulation Systems) (n=9) ; titanium anchor (3550-39) (Medtronic) (n=10). An increasing weight was applied to the lead and its movement observed by an investigator blinded to the force applied.

Results

There was a significant difference in applied force to produce lead movement between anchor types (2 –way ANOVA, $F = 11.04$, $p < 0.001$). There was a significant difference between the Titanium anchor and the silastic anchors ($p < 0.003$). There was a significant difference between long and short silastic anchors ($p < 0.01$).

There was no significant difference in force to cause lead movement between the operators (unpaired t test for samples of unequal variance, $t = 0.15$, $p = 0.88$)

Conclusion. In this cadaveric investigation we have found a difference in the force required to cause lead movement within its anchor as a function of the anchor type. A greater force could be applied to leads anchored with long compared with short silastic anchors and a greater force still could be applied to leads anchored with Titanium anchor compared with the silastic anchors.

Monday, December 10

1540-1547

Marquesa III-IV (16)

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

3. Endoscopic Epidurolysis as tool to show the different morphological characteristics of the Failed Back Surgery Syndrome, and to predict the response to Spinal Cord Stimulation

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Introduction

Spinal Cord stimulation (SCS) devices are frequently used for pain therapy. Actually a validated method for the prediction of the success of this technique is missing. In this study we analyzed morphological endoscopic images of patients suffering from severe chronic back pain with or without radiculopathy, resulting from spinal stenosis (ST), or failed back surgery syndrome (FBSS); in order to assess if it is possible to define the response to SCS from the observation of the dura morphology.

Materials and Methods

Patients suffering from chronic (from at least 6 months) low back pain with or without radiculopathy, who had been previously treated pharmacologically and with invasive approaches with little or no benefit (for less than 3 months); were selected for this study. All patients were studied with radiodiagnostic, and electrophysiological methods. Endoscopic images were used for the investigation of morphological elements. 6 months after the implantation of the SCS device, the response to the SCS was assessed and correlated to morphological images.

Results

66% of patients with FBSS and 55% of ST had a constant pain relief. The presence of different abnormal and pathological morphologies was noted in the epidural space. Patients with distension of the dura due to adhesive fibrosis (functional instability) had a response to SCS < 30%; whereas, patients with a dura hyperalgesia due to flogosis, perineural fibrosis, or vassal stasis had the best (70%) response to SCS.

Conclusion

This study shows that the response to SCS is correlated to the type of spinal pathology. Patients suffering from low back pain due to spinal stenosis or FBSS can have different pathological morphology of the dura, resulting in different response to the SCS. We believe that the greatest response can be observed in patients with neuropathic pain without mechanical functional instability.

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Acknowledgements

We acknowledge the Institute of Algological Science (ISAL) for the sponsorship, and all the subjects who took part in the study.

Learning Objectives:

1. To evaluate if patients suffering from chronic back pain, who and presenting normal radiodiagnostic and neurophysiological examinations, nonetheless, have pathological morphological aspects of the dura;
2. To determine if the epiduroscopy can be a tool to study dural morphological components in patients suffering from post-surgical or other chronic back pain pathologies;

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

3. To define the therapeutic benefits that can be expected from the endoscopic procedure, and which is the best procedure that should be adopted in every pathological condition.
4. To assess if the epiduroscopy can be a good tool for the prediction of the response to SCS

Monday, December 10

1550-1557

Marquesa III-IV (16)

4. Rechargeable Spinal Cord Stimulation (SCS) with Zero Volt™ Battery Technology: a Case Report

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Introduction

While rechargeability in neurostimulation devices has expanded capabilities for implantable pulse generators (IPG), battery longevity and capacity can be compromised by depletion and disuse, and so patient compliance with a recharging regimen must be considered during device selection. Zero-Volt™ battery technology in a rechargeable SCS device can minimize concerns about patient compliance. We report on a case of long-term IPG dormancy, in which the IPG was not impacted by patient noncompliance with recharging.

Materials and Methods

A 50-year old man diagnosed with CRPS after Morton's neuroma removal in 2000 and 2001 presented with bilateral lower extremity pain. Rated at 7-8 on a numeric analog scale, the pain spanned the anterior half of both feet on the dorsal and plantar surfaces. In 2005, the patient was implanted with two 8-contact percutaneous leads parallel to the midline at T11-12 vertebral level and a rechargeable IPG with a Zero-Volt™ battery (Boston Scientific Neuromodulation, Valencia, CA). The patient reported 100% paresthesia coverage in the painful areas and a pain rating of 3-4. In 2007, the patient stopped using the stimulator for 4 months due to a "nonfunctioning" remote control. Consequently, the battery of the IPG completely discharged, and entered hibernation mode, in which no stimulation was delivered and the stimulator was dormant.

Results

After 4 months of hibernation, the patient visited the clinic requesting restoration of stimulation for pain relief. The "non-functioning" remote control merely required new batteries. The IPG was successfully recharged, and the previously selected programs were accessed. Moreover, the battery sustained no damage; the capacity and time-between-recharge were as they had been prior to the hibernation period.

Conclusion

The incorporation of Zero-Volt™ rechargeable battery technology into our patient's SCS IPG allowed a long period of disuse without impact to the system's capability, and may have avoided or delayed surgery to replace the IPG.

Learning Objectives:

1. The potential compromise of rechargeable battery longevity and capacity by depletion and disuse
2. The potential importance of patient compliance with recharging SCS
3. The ability of Zero-Volt™ technology to address compliance challenges

Monday, December 10

1630-1637

Marquesa III-IV (16)

5. Methods to Minimize Neurostimulator Leadwire Heating During MRI Scans

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Introduction

Magnetic Resonance Imaging (MRI) scans are generally contraindicated by both neurostimulator device and MRI equipment manufacturers. However, MRI has become one of medicine's most important diagnostic and clinical tools. A major concern with conducting MRI scans on a neurostimulator patient is the potential for overheating of the implanted leadwires and/or distal tip electrodes. It has been reported that such overheating can cause severe burns or even death in rare cases. This paper evaluates whether certain combinations of leadwire geometry, lead length, position in the MRI bore, and certain scan sequences can lead to worst-case leadwire heating.^{1,3} Also, we evaluated 1.5 Tesla (T) and 3.0T design refinements of a resonant inductor capacitor (L-C) bandpass filter chip at the distal electrode tip(s) designed to create a high impedance at the MRI-RF pulse frequency in order to reduce the flow of radio frequency (RF) current and thereby reduce leadwire heating.²

Materials and Methods

Real-time temperature rise maps were obtained by moving a human gel phantom containing a functional neurostimulator with its leads around inside the MRI scanner while its distal electrode was instrumented with fiber optic temperature probes. Various lead lengths, layouts and MR scan sequences were tested. Three dimensional color maps were created showing areas of maximum RF field coupling and maximum heating. Once these worst-case positions were determined, special prototype leads were built with the L-C resonant bandpass filter chip installed in the distal tip electrode and the temperature measurements were repeated at the predetermined worst-case position.

Results/Conclusion

Temperature mapping of 1.5T and 3.0T MRI scanners resulted in worst-case distal tip temperatures of 57°C and 95°C respectively. Identical leadwires that incorporated the L-C resonant filter were tested in the same worst-case positions and exhibited a reduction in distal tip temperature of approximately 90% (down to 2.7°C), providing a high safety margin.

References - Oral presentations at major conferences (also see attached list):

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Acknowledgements

Johns Hopkins University, Dr. Henry Halperin, MD and Dr. Menachem 'Muz' Zviman, Baltimore, MD.

Learning Objectives:

1. Realize that a few safe MRI scans on neurostimulator patients does not mean that all scans can be considered safe.
2. Understand the variability of electric field and induced currents in implanted leadwires in a typical MRI bore
3. Understand a new passive component chip design that eliminates concern about lead wire heating due to MRI.

Monday, December 10

1640-1647

Marquesa III-IV (16)

6. Comparison of intra-operatively mapping of sensory responses of a single channel surgical lead versus a dual channel surgical lead and evaluation of the implantation technique. Preliminary results of the Respec study.



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

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Introduction: Surgical electrodes for spinal cord stimulation (SCS) have technical advantages compared to percutaneous electrodes (1). For SCS in case of failed back surgery syndrome it is still not proven if a dual channel lead is more effective than a single channel lead (2).

Materials and Methods: The Respec study is a prospective, randomised, controlled study with a one year follow up period. Thirty patients with failed back surgery syndrome with both low back pain and pain in at least one leg are randomised into the single channel arm (Resume lead- Medtronic) and the dual channel lead arm (Specify lead- Medtronic). During the implantation of the lead however, in each patient both Resume and Specify leads are tested intraoperatively (mapping of sensory responses at different levels and with different lead settings). To have a fully cooperative patient during the surgical procedure and the sensory mapping, spinal anaesthesia is used in combination with a minimal invasive, unilateral approach (Duffel technique)(3).

Results: So far 16 patients have undergone the intraoperative mapping. The effectiveness of the Specify lead to provoke paresthesias in the lower back and the buttock is the best at the level D8D9 and superior to the Resume lead. For the lower limbs, the effectiveness of the Resume lead at the level D9D10 is slightly higher. Using the Duffel technique for implantation, we have had no complications and all patients left the hospital at least at the second day following the implantation.

Conclusion: These first, preliminary results show already a distinction between the two types of electrodes and the level of implantation. The statistical analysis of all 30 patients and the long term results are to be awaited. The used implantation technique causes no technical restrictions for this procedure.

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Acknowledgements

We gratefully like to acknowledge the financial support of Medtronic for the Respec study.

Learning Objectives:

1. to show that , in spinal cord stimulation, peroperative sensory mapping is imperative for a good outcome.
2. to show that level of electrode implantation and choice of type of electrode can influence outcome
3. to show that a minimal invasive implantation technique for surgical electrodes has advantages and no technical limitations

Monday, December 10
1650-1657
Marquesa IIII-IV

7. Differences between staggered and parallel percutaneous lead tripole arrays: preliminary findings from a prospective post-market study.

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Vytas Rumpinkas

Introduction



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Spinal cord stimulation (SCS) is a popular treatment modality for chronic pain, especially for patients with Failed Back Surgery Syndrome and other types of back pain. However, stimulation coverage of axial pain is often difficult to obtain and/or maintain. The following data present findings on two different percutaneous tripolar leads configurations.

Materials and Methods

Data is being collected from an ongoing clinical research study being conducted with patients implanted with the Eon[®] Neurostimulation System (ANS; Plano, TX). This study is a prospective, multi-centered, 2-year post-initial programming study. After informed consent is obtained, the patients are evaluated prior to system implant, and then return for evaluation at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years post implant. The following parameters are evaluated during the study: patient reported pain relief, patient reported satisfaction level, patient reported area of paresthesia coverage of their painful area, lead placement, device programming, patient quality of life, and patient disability.

Results

Data presented consists of preliminary results from patients enrolled and implanted with percutaneous lead tripole arrays.

Conclusion

Patients with parallel tripole configurations generally had better outcomes and higher satisfaction and quality of life improvements than those with a staggered configuration.

Acknowledgements

The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:

1. Understand the difficulties in stimulation coverage of low back pain.
2. Recognize the different forms tripolar arrays may take.
3. Recognize the advantages of transverse tripolar programming

Monday, December 9

1700-1707

Marquesa III-IV (16)

8. Awake versus non-Awake Surgery for placement of Spinal Cord Stimulators

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Introduction: The efficacy of spinal cord stimulation (SCS) is predicated upon producing overlap of paresthesia coverage and the painful region. Patients will typically undergo awake surgery for permanent implantation of SCS to try to optimize the distribution of paresthesia as mentioned above. Over the last three years, permanent implantation of SCS is performed under general anesthesia with intra-operative electrophysiology and fluoroscopy to localize optimal electrode position. Additionally, all patients will have underwent a percutaneous trial prior to permanent implantation.

Materials and Methods: A retrospective review of 838 internalization operations to determine whether first time awake surgery for placement of spinal cord stimulators is preferable to non-awake placement. Patients between 2000-2007 implanted by two physicians at a single center were studied.

Results: Based on this review there was a 50% failure rate with awake surgery compared to a 38% rate for non- awake patients. First time awake surgery was associated with 0.47 more operations. Overall 74% of failures arose from electrode malfunctions, of which 87% of these were without any history of trauma as obtained from the patients. There was a trend towards more infection occurring in awake versus non- awake patients. Operating time and patient satisfaction was also assessed.

Conclusion: Non-awake surgery is associated with fewer failure rates and therefore fewer re-operations, making it a viable alternative. Any benefits of awake implantation should carefully be considered in the future.



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Learning Objectives:

1. The efficacy of spinal cord stimulation (SCS) is predicated upon producing overlap of paresthesia coverage.
2. Benefits of SCS implantation under general anesthesia make it a viable alternative.

Monday, December 9

1710-1717

Marquesa III-IV (16)

9. Efficacy of the Lamitrode[®] Tripole[™] 8 surgical lead: Preliminary findings from a prospective post-market study.

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Introduction

Spinal cord stimulation (SCS) is a popular treatment modality for chronic pain, especially Failed Back Surgery Syndrome. However, stimulation coverage of axial pain is often difficult to obtain and/or maintain. The Lamitrode[®] Tripole[™] 8 leads (ANS; Plano, TX) are paddle leads designed for hard-to-cover back pain.

Materials and Methods

Data is being collected from an on going clinical research study being conducted with patients implanted with the Eon[®] Neurostimulation System (ANS; Plano, TX). This study is a prospective, multi-centered, 2-year post-initial programming study. After informed consent is obtained, the patients are evaluated prior to the system implant. Patients then return for evaluation at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years post implant. The following parameters are evaluated during the study: patient reported pain relief, patient reported satisfaction level, patient reported area of paresthesia coverage of their painful area, device programming, patient quality of life, and patient disability.

Results

Data presented is preliminary results from 10 patients enrolled at one clinical site who have completed evaluations through the 1 year visit.

Conclusions

The Tripole[™] configuration allows use of anodal guarding to confine the stimulation to desired fibers, which allows a broad amplitude range between perception and discomfort thresholds. The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:

3. Understand the difficulties in stimulation coverage of low back pain.
4. Recognize the advantages of in-line transverse tripolar programming.

Monday, December 10

1720-1727

Marquesa III-IV (16)

10. Cognitive and Affective Effects of Neuromodulation on Quality of Life

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Andrew Brooks, B.S.

Introduction

For some time neuromodulation has been a core surgical procedure applied in the treatment of movement disorders (e.g., Parkinson disease), neuropathic pain, and epilepsy. There are now close to 100 studies on its effects: Neuromodulation has been shown to successfully reduce symptoms in patients with these disorders. That said, the reduction in symptoms alone does not necessarily translate into an

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

improved QoL. Further, extant data suggest that cognitive and affective factors are implicated in QoL change after treatment in neuromodulation patients. Specifically, cognitive and affective change is well-established with VNS; less so with DBS; and only to a mild degree with SCS.

Materials and Methods

At this center, pilot cognitive and affect data as well as QoL information on 20 neuromodulation patients suggest: (1) that there is considerable variability in cognitive status; (2) that 15/20 have cognitive problems; (3) that 14/20 have significant depression symptoms; and (4) that QoL differs among the groups. Prospectively, within the year we will more gather data on the pre-treatment, a post-treatment, and a 3-month follow-up on 50 neuromodulation patients (DBS, VNS, DCS) ages 20-85. Our test battery includes psychological measures, including RBANS, Trails A&B, the Stroop Color Word Test, MBMD, BDI-II, SAST, SF-36, and health markers. Standard mediation analysis will be used to determine the mediating role of cognition and affect on QoL.

Results

Preliminary data confirm the previous findings and indicate that affect and cognition mediate QoL; that the three groups do differ on these measures; and those with more cognitive problems or more depression/anxiety experience a reduced QoL in spite of better pain and health markers.

Conclusion

The study seeks to clarify the role of cognition and affect on QoL, determine whether SCS or DBS patients improve on cognition and affect, and determine predictors of positive QoL change in neuromodulation patients.

References

Richter EO, Hyer LA, Brooks A, Noorani SP, Toole MR, Robinson JS. Cognitive and Affective Effects of Neuromodulation on Quality of Life.

Learning Objectives:

1. Understand the role of cognition and affect on neuromodulation outcome.
2. Determine the best predictors for an improvement in Quality of Life.
3. Compare cognitive, affect, and Quality of life change between neuromodulation types.

Tuesday, December 11

0700-0707

Princesa Ballroom B-C (13)

1. Neuromodulation in dysphagia induced by surface electrical stimulation to suprahyoid muscles area

Kosei Mitsuhashi, Ph.D.

Kazunori Seki, MD, PhD, Takahide Ogura, PhD, Yasunobu Handa, MD, PhD

Introduction

Electrical stimulation is used as an effective treatment for dysphagia^{[1] [2]}. However, Electrical stimulation to the skin surface above the larynx during swallowing could cause aspiration because of interference with laryngeal elevation, which plays an important role in airway protection. We describe surface electrical

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

stimulation at rest which induces simultaneous elevation of the hyoid bone and larynx and thus, resulting in improvement of dysphagia.

Materials and Methods

Six healthy subjects and six dysphagic patients participated in this study. Stimulation electrodes were attached on the skin above the suprahyoid muscle area on both sides. Cyclic stimulation for 15min with 5sec ON and 5sec OFF using bipolar rectangular pulse was applied to each subject. Stimulation frequency was 3Hz and the amplitude was set to the intensity just below pain threshold in each subject. In six healthy subjects, Movement of the hyoid bone and larynx during suprahyoidal surface stimulation was investigated videofluoroscopically and analyzed their trajectory and time sequence by a computer. Movements of the hyoid bone, epiglottis, and larynx during swallowing were detected videofluoroscopically before and after suprahyoidal surface electrical stimulation using barium jelly in dysphagic patients.

Results

Elevation of the hyoid bone and larynx synchronized with the 3Hz stimulation was observed in healthy subjects. After suprahyoidal surface electrical stimulation, movement distance of the hyoid bone and larynx during swallowing was significantly increased in every patient. An interval between bolus entry to the vallecula epiglottica and initiation of swallowing reflex was shortened and the swallowing reflex itself was enhanced after suprahyoidal surface electrical stimulation (Figure 1 and 2).

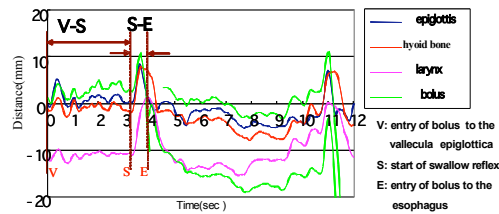


figure 1

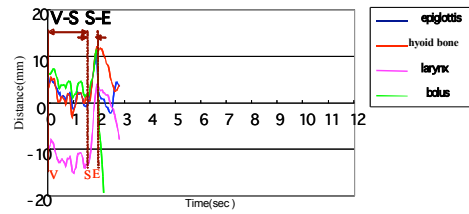


figure 2

Conclusion

Suprahyoidal surface electrical stimulation applied before swallowing increased movements of the hyoid bone and larynx and improved swallowing disturbance in dysphagic patients. Our result suggests that neuromodulatory effects via suprahyoidal surface electrical stimulation might play an important role in such improvement of dysphagia.

References

- [1] Freed ML, Freed L, Chatburn RL, Christian M. Electrical stimulation for swallowing disorders caused by stroke. *Respir Care*. 2001.46(5):466–474.
- [2] Ludlow CL, Humbert I, Saxon K, Poletto C, Sonies B, Crujido L. Effects of Surface Electrical Stimulation Both at Rest and During Swallowing in Chronic Pharyngeal Dysphagia. *Dysphagia*, 2006.May 23.

Figure and Table Legend

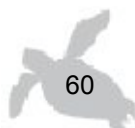
Figure 1 : Movement analysis of the hyoid bone and larynx during swallow. dysphgic patient(case A) before suprahyoidal surface electrical stimulation.

Figure 2 : Movement analysis of the hyoid bone and larynx during swallow. dysphgic patient(case A) after suprahyoidal surface electrical stimulation.

Learning Objectives:

1. To clarify the movements of the hyoid bone and the larynx induced by surface electrical stimulation to suprahyoid muscles area.
2. To assess the swallow function in dysphagic patients after suprahyoidal surface electrical stimulation.

Tuesday, December 11
0710-0717
Princesa Ballroom B-C (13)



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

2. Improvement of swallowing movement after electrical stimulation to lower leg acupoints in poststroke patients

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Yasunobu Handa (MD PhD), Kazunori Seki (MD PhD), Takashi Seki (MD PhD), Hiroyuki Arai (MD PhD)
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Introduction

Impairment of the swallowing function is a significant factor in developing silent aspiration, which may cause fatal aspiration pneumonia in poststroke patients¹⁾. Because of some limitations in the use of oral medications due to side effects, dysphagia, or feeding difficulties, nonpharmacological approaches have been investigated to restore the swallowing function²⁾. We tried a treatment consisting of transcutaneous electrical stimulation applied through electrodes placed on two lower leg acupoints.

Materials and Methods

Eight poststroke patients (4 women, mean age 77.6 (SD 5.59) years) in chronic stage were selected. Their strokes had occurred a mean of 48.0 (SD 32.9) months before the test, and all of them experienced episodes of choking while eating or drinking. Electrical stimulation (15Hz, 15minutes) was administered with hand-held battery-powered electrical stimulators connected to the surface electrodes positioned on two acupoints, Zusanli (ST-36) and Taixi (KI-3), of both lower legs. These acupoints were selected based upon original descriptions of traditional Chinese medicine³⁾. The treatment was done three times a week for four weeks. To evaluate the swallowing function, we measured the required time for swallowing movement (RTSM), which was defined as time from the injection of 1 mL of distilled water into the pharynx through a nasal catheter to the end of swallowing movement. The RTSM before and after electrical stimulation was compared with Wilcoxon signed-rank test.

Results

As shown in Figure 1, there were significant improvements in the RTSM (mean 15.26±8.04 vs. 6.68±3.94seconds, $P<0.05$) after four weeks of electrical stimulation to the lower leg acupoints.

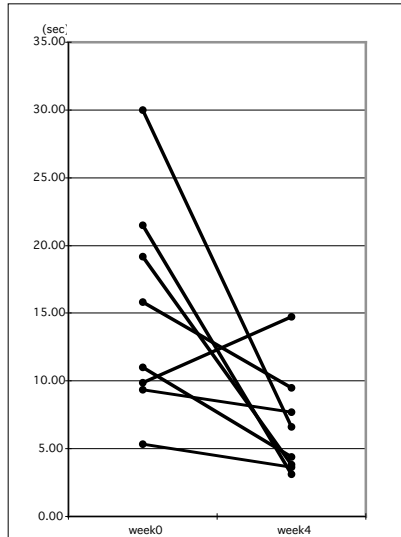


Figure 1. The required time for swallowing movement in poststroke patients at baseline (week 0) and after four weeks of electrical stimulation (week 4).

Conclusion

It was suggested that the electrical stimulation to the lower leg acupoints could improve the swallowing movements of stroke patients in chronic stage. It has been said that existing modalities for treating

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

dysphagia are generally ineffective⁴). Therefore electrical stimulation to the lower leg acupoints may be a promising treatment for poststroke patients suffering from dysphagia.

References

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Tuesday, December 11

0720-0727

Princesa Ballroom B-C (13)

3. The Chemical Stabilities of Admixtures Containing Ziconotide and Fentanyl or Ziconotide and Sufentanil During Simulated Intrathecal Administration

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Introduction

The chemical stability of a combination of intrathecal analgesics may affect the dose actually delivered and the frequency of pump refills. This investigation characterized the chemical stabilities of admixtures containing ziconotide and either fentanyl or sufentanil under simulated clinical conditions.

Materials and Methods

Admixtures containing 25 mcg/mL ziconotide and 1000 mcg/mL fentanyl citrate or sufentanil citrate were prepared from commercially available ziconotide (25 mcg/mL) and powders of the opioid drugs, then sparged with nitrogen to remove residual oxygen. Implantable intrathecal pumps that had been previously exposed to ziconotide were rinsed twice with 5 mL of admixture, then filled with 20 mL of admixture and stored at 37°C. Drug concentrations were determined with reverse-phase high-performance liquid chromatography from samples collected within minutes of pump fill (Day 0) and at varying intervals over the next 40 days. The percentages of the Day 0 drug concentrations at each sampling point were plotted versus time, and 95% confidence intervals (CI) were determined for the linear regression of percent initial concentration versus time.

Results

At study end (Day 40), ziconotide concentrations averaged 87.5% of initial in the ziconotide-fentanyl admixture and 89.3% of initial in the ziconotide-sufentanil admixture; opioid concentrations remained at 100% of initial. In the ziconotide-fentanyl admixture, the lower 95% CI for the percentage of the initial ziconotide concentration intersected the 90% specification at 26 days and the 80% specification at 58 days. In the ziconotide-sufentanil admixture, the lower 95% CI intersected the 90% and 80% specifications at 33 days and 68 days, respectively.

Conclusion

When combined with fentanyl (1000 mcg/mL), ziconotide (25 mcg/mL) was 90% stable for 26 days and 80% stable for 58 days. When combined with sufentanil (1000 mcg/mL), ziconotide (25 mcg/mL) was 90% stable for 33 days and 80% stable for 68 days. The opioids remained 100% stable throughout the study.

Acknowledgements

These experiments were sponsored by Elan Pharmaceuticals, Inc.

Learning Objectives

1. Recognize the importance of chemical stability when selecting combinations of intrathecal medications
2. Estimate the stability of ziconotide when combined with fentanyl or sufentanil

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

3. Estimate the stability of fentanyl or sufentanil when combined with ziconotide

Tuesday, December 11

0730-0737

Princesa Ballroom B-C (13)

4. Neuromodulation of the epileptic focus for intractable seizures originating in non lesional eloquent areas

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Francisco Velasco, MD

Introduction: Neuromodulation for intractable seizures has been applied in different targets: centromedian (Velasco AL, et al (2006) *Epilepsia* 47:1203-1212) or anterior thalamic (Kerrigan JF, et al (2004) *Epilepsia* 45:346-354), cerebellar (Velasco F, et al(2005) *Epilepsia* 46:1-11), vagus nerve stimulation (Amar AP, et al (2004) *Neurosurgery* 55:1086-1093). Epilepsy surgery in non-lesional patients with intractable focal seizures originating in eloquent areas constitutes an important problem epileptologists have to deal with specially because there is a high risk of neurological sequelae. Neuromodulation could be an alternative non-lesional surgical method in these cases.

Materials and Methods: The study was approved by the Ethical and Research Committees of the General Hospital. A total of seven patients were included, five of them with mesial temporal lobe epilepsy, one with supplementary motor area seizures and one with motor seizures. They signed an informed consent. Patient and caregiver were trained to have a reliable seizure count. They underwent neuropsychological testing, EEG. All of them had normal magnetic resonance imaging. They underwent intracranial electrode or grid implantation to localize the precise site of focus. Once it was localized, diagnostic electrodes were used as guides to implant permanent electrodes for brain stimulation. High frequency stimulation was used. Follow-up was performed 3-6-12 months with seizure count, EEG and neuropsychological tests to evaluate performance.

Results: All patients showed seizure reduction between 90 to 100%. None of them showed neurological impairment and their neuropsychological tests either remained same as baseline or showed improvement.

Conclusion: Neuromodulation is a non-lesional reversible method which reduces seizures without impairing neurological function in patients with mesial temporal or motor area epilepsy.

Learning Objectives

1. Establish the criteria for patient selection
2. Precise the stimulation target for chronic neuromodulation
3. Support the conservation of verbal and non-verbal memory

Tuesday, December 11

0740-0747

Princesa Ballroom B-C (13)

5. Vagus Nerve Stimulation for the Treatment of Intractable Epilepsy

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Introduction

To explore the effectiveness and mechanism of VNS therapy in intractable epilepsy.

Materials and Methods

Vagus Nerve Stimulation were performed in eleven patients from April 2004 to December 2006, three patients with secondarily generalized partial seizures after cephalitis (multi-lesion), three patients with Lennox-Gastaut Syndrome (LGS), others with generalized seizures. All patients have tried more than two antiepilepsy drugs without effect. The operations were conducted under general anaesthesia, 3cm long incision was made in the front of left sternocleidomastoid near thyroid cartilage. Left vagus nerve stem was

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

exposed, gyrate electrode of VNS device was wrapped the cervical vagus nerve stem. The skin incision was made in left side of the chest wall and VNS generator was implanted, electrode was connected with generator and fixed. The generator was turned on 2 weeks after operation. Stimulation parameters were 30seconds ON and 5minutes OFF, the frequency was 30Hz, and the pulse width was from 500_s to 1000_s. The output currents adjusted from 0.25mA to 1.5mA⁽¹⁻³⁾.

Results

After 0.5~2 years of intermittent stimulation of the left vagal nerve, the seizure frequency was reduced by 60% occurred in all patients. Tonic-clonic seizures were significantly controlled and the seizure severity was alleviated significantly. Neuropsychological test showed a moderate improvement in mental functioning, behavior, and mood.

Conclusion

VNS is a minimal invasive surgery with few side effects, Which can obviously reduce seizure frequency. And can greatly improve the quality of life in patients with epilepsy. It is also an alternative and better way for patients with refractory epilepsy⁽⁴⁻⁶⁾.

References

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- 2.Murphy JV. Left vagal nerve stimulation in children with medically refractory epilepsy. *The Journal of Pediatrics*. 1999; 134:563-566
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Learning Objective:

1. The goal of this research is to improve the therapeutic effects and the making of VNS system by study the correlativity between the parameters of VNS and the frequency of epileptic discharge.

Tuesday, December 11
1400-1407
Princesa Ballroom B-C (13)

1. Efficacy of Extradural Motor Cortex Stimulation in Advanced Idiopathic Parkinson's Disease: The Experience of the Functional Neurosurgery Study Group of the Italian Neurosurgical Society

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Cioni Beatrice, Dario Alessandro, Landi Andrea, Meglio Mario, Sturiale Carmelo, Zeme Sergio, Romanelli Pantaleo, De Rose Marisa, Antonini Angelo, Bentivoglio Annarita, Mariani Claudio, Valzania Franco, Pagni Carlo Alberto

Introduction

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Extradural Motor Cortex Stimulation (EMCS) was recently attempted to treat different movement disorders: we report the results obtained by the Italian Functional Neurosurgery Study Group on Parkinson's disease (PD).

Materials and Methods

41 patients affected by advanced idiopathic PD were enrolled: they were either not eligible for or refused DBS. All patients had long history of disease (5–22 years, mean 13.95 +/-4.97 yrs). They scored III to V on Hoehn-Yahr scale. The score of the UPDRS off-medication was 49-120 (mean 91.173 + - 22.189). Quadripolar plate electrode (Model 3587A; Medtronic, Inc.) was introduced in extradural space over hand motor area of one hemisphere usually contralaterally to the worst clinical side. 8 cases were implanted bilaterally: only results of the unilateral stimulation will be reported. Clinical assessment was performed by UPDRS at 1, 3, 6, 12 months and then at least every 6 months in various conditions: a. before implantation: baseline evaluation off-medication/off-stimulation. b. during treatment: on-medication/on-stimulation and off-medication/on-stimulation. The follow-up varied from 6 months to 3 years.

Results

Stimulation induced significant improvement in total UPDRS score ($p < 0.050$ Wilcoxon-test) and in UPDRS III score (up to 23.12%, $p < 0.02$) in off-medication condition; improvement was mostly observed in activities of daily living (ADL), posture, gait, balance, bradykinesia, speech and facial expression (UPDRS III, items 27-28-29-30-31). Clinical benefits were more evident in most affected patients, whose quality of life improved, requiring less care-giving too. In addition, according to UPDRS IV data, there was marked attenuation of levodopa-induced dyskinesias persisting throughout one year follow-up. Antiparkinsonian drugs intake showed a trend to reduction although not statistically significant.

Conclusion

Unilateral EMCS relieves mostly above axial symptoms, ADL and L-dopa induced dyskinesias. Italian clinical experience adds favorable data to enlarge the series of parkinsonian patients treated by EMCS.

References

Pagni C.A, Zeme S., Zenga F. Maina R. Extradural motor cortex stimulation in advanced parkinson's Disease: the Turin experience, Neurosurgery 2005 Suppl 3: 402-403

Learning objectives:

- 1) New target in Brain Stimulation for PD
- 2) Results of Extradural Motor Cortex Stimulation in advanced PD
- 3) Motor Cortex Stimulation vs DBS in PD

Tuesday, December 11

1410-1417

Princesa Ballroom B-C (13)

2. Electrical Stimulation of Hippocampus (ESH) in Patients with Intractable Temporal Lobe Epilepsy: A Long Term Follow Up Study

Guillermo Castro Farfan

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Ana Luisa Velasco, Francisco, Velasco Campos, Marcos Velasco

Introduction

Evaluation of ling efficacy of ESH in the treatment of complex partial seizures in nine patients with intractable mesial temporal lobe epilepsy was performed

Materials and Methods

All Patients had a 6 months basal period (for seizure diary collection and neurological testing) after which they underwent bilateral hippocampal electrode implantation to establish focus laterality and location. 3 patients had bilateral and 6 had unilateral foci. Diagnostic electrodes were explanted and definitive Medtronic electrodes were implanted directed to the hippocampal foci. Position was confirmed with MRI and afterwards the DBS system internalized. Patients signed the informed consent approved by the Hospital's

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Ethics committee and started a double blind stimulation protocol. Patients attended every 3 months for seizure count and neuropsychological test.

Results

Follow up went from 18 months to 5 years. Patients were divided in two groups: 5 had normal MRIs and seizure reduction of >95%. 4 had hippocampal sclerosis and seizure reduction of >50%. None had neuropsychological deterioration. No patient showed adverse effects. 1 patient was explanted after 2 years due to skin erosion in the trajectory of the system.

Conclusion

ESH provides a non lesional method that improves seizure outcome without deterioration of memory in patients with hippocampal epileptic foci.

Learning Objectives:

1. Alternative reversible neurosurgical technique (neuromodulation) evaluation.
2. Conserving cognitive functions in epilepsy.

Tuesday, December 11

1420-1427

Princesa Ballroom B-C (13)

3. Accuracy of stereotactic electrode placement in deep brain stimulation

Wilhelm Eisner, PhD, Department of Neurosurgery, Innsbruck Medical University, Innsbruck, Austria

SOHM Florian, M.D., FEUCHTNER Gudrun, M.D., BAUER Richard, M.D., ANTON Juergen-Volker, M.D., TWERDY Klaus, Prof., M.D., EISNER Wilhelm, M.D.

Introduction

In this study, we report in vivo measurements of the accuracy of stereotactic electrode placement in patients undergoing DBS electrodes by using intra- and post-operative computed tomography (CT). The position of the implanted electrode and their contacts were measured and compared with the planned position.

Materials and Methods

24 patients with movement disorders (Parkinson disease (n = 7), tremor (n = 10), dystonia (n = 7)) treated with bilateral deep brain stimulation (DBS) (overall 48 target points) were investigated [1, 2, 3]. The target point of the electrode was planned stereotactically in combination with a pre-operative stereotactic helical computed tomography (CT). A post-operative CT was performed in order to control the position of the electrodes in relation to the previously planned target point. The position of the four electrode contacts (Medtronic 3387 or 3389, Inc.) was measured according to the Talairach space (AC-PC line) and compared with the coordinates of the planned target point.

Results

The mean minimal distance is 1.39 mm (SD = 0.86 mm) and ranges from 0 to 4.5 mm. The average absolute deviation from pole 0 is in x axis 1.71 mm, in y axis 1.43 mm and in z axis 1.88 mm. The mean euclidian distance (distance target point to tip of the electrode) is 3.26 mm (SD = 1.77). You have to keep in mind that different electrode sizes were used. Therefore the electrode contacts can cover a range up to 10.5 mm.

Conclusion:

This study demonstrates the accuracy of stereotactic electrode placement. The error in this patient related investigation is not much larger than in phantom studies [4, 5]. Nevertheless there should be caution regarding patients with a large atrophy and much loss of liquor.

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

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5 Maciunas RJ, Galloway RL, Latimer JW. The application accuracy of stereotactic frames. *Neurosurgery* 1994.35:682-695.

Learning Objectives:

1. Stereotactic electrode placement is an accurate procedure.

Tuesday, December 11

1430-1437

Princesa Ballroom B-C (13)

4. Pulsed Radiofrequency of the Stellate Ganglion for the Treatment of Hemicrania Continua: A Case Report

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Introduction

According to the International Headache Society, hemicrania continua is a chronic, unilateral, unremitting headache lasting greater than 5 months and associated with autonomic features such as rhinorrhea, ptosis, and lacrimation (1). Pulsed radiofrequency (RF) has been used with various success in the treatment of cervical and lumbar radiculopathy (2,3,4), occipital neuralgia (5), trigeminal neuralgia (6) and post-traumatic headache (7). We present a first case of RF for the treatment of hemicrania continua.

Materials and Methods

23-year-old female presented to our clinic complaining of severe, chronic, persistent, right hemicranial headaches associated with brief episode of severe stabbing and burning pain as well as nasal congestion, ipsilateral lacrimation, and ptosis. The patient was subsequently diagnosed with hemicrania continua and was given a trial of indomethacin, melatonin, topamax, and multiple narcotic analgesics. Unfortunately, medical management was not successful and patient underwent a series of right stellate ganglion blocks. Patient had a total of four blocks using 6mg of betamethasone and 1% lidocaine, each providing 100% relief of pain for 10 days. After a 10 day interval, headache would return to its previous baseline of 7/10 on VAS. Pulsed radiofrequency was then contemplated and performed in order to provide patient with longer relief from her pain. A 50000 Hz current in 20-millisecond pulses at a frequency of 2 per second was applied for a total of 720 seconds to C6 and C7 uncinatate processes using fluoroscopic guidance. This was followed by the injection of betamethasone and lidocaine in the manner identical to previously performed blocks

Results

Immediately after the procedure, patient developed right Horner's syndrome and conjunctival engorgement. Headache was 100% relieved in the same fashion it was following previous stellate blocks. After approximately 4 hours right Horner's resolved. Patient had complete resolution of pain at 10 days, 30 days, 60 days, and at the last follow-up at 120 days.

Conclusion

Pulsed RF has been employed for a variety of diagnoses including post-traumatic headaches and facial pain associated with trigeminal neuralgia. The results have been mixed and even the basic premise of this procedure has been challenged (8,9). This is the first reported case of stellate ganglion pulsed RF for the treatment of hemicrania continua. Based on this singular report, pulsed RF may indeed be beneficial for the treatment of hemicrania continua, when other options have been exhausted.

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Learning Objectives:

1. Present a novel approach to the treatment of hemicrania continua using pulsed radiofrequency

Tuesday, December 11

1440-1447

Princesa Ballroom B-C (13)

5. Parkinsonian movements in model and experiment

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Introduction

Parkinson's disease (PD) is known to originate from a degeneration of dopaminergic neurons in the substantia nigra. One of the most debilitating aspects of PD is the inability to initiate and execute voluntary movements (bradykinesia and akinesia). PD patients are particularly impaired in the performance of complex movements, e.g. simultaneous and sequential motor tasks. Despite a huge amount of anatomical and physiological data regarding the structure of the basal ganglia and their connections, the computational processes performed by the basal ganglia in health and disease remain unclear [1-5].

The goal of the current research is to develop a mathematical model of the functional scheme of the 'motor' basal ganglia-thalamocortical circuit. In addition, an experimental study is set up to investigate movements performed by PD patients, and the effectiveness of DBS.

Materials and Methods

Model

The model of the 'motor' basal ganglia-thalamocortical circuit investigated the interaction between two competing motor channels, controlling two movement directions (flexion/extension). PD was simulated as a reduction in the level of dopamine, as well as a loss of functional segregation.

Experiments

The measurements consisted of a series of movements, ranging from a simple movement to sequential movements, and several UPDRS tests. The movements are registered using accelerometers.

Results

The primary deficits in movement resulted directly from dopamine loss. Loss of functional segregation contributed to the bradykinetic symptoms, due to a reduced ability to suppress unwanted movements. It also led to excessive neurotransmitter depletion, affecting the performance of sequential movements. Similar trends were observed in movement time and peak velocity in the simulated and experimental data.

Conclusion

The results of the present research should advance the understanding of the role played by the basal ganglia in motor control, as well as the causes of the deficits seen in Parkinson's disease and the effectiveness of DBS.

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Learning Objectives:

1. Role of Basal Ganglia in motor control and causes of bradykinesia and akinesia.
2. Comparison of movement (simple and complex) in healthy subjects and Parkinson's patients.
3. Effectiveness of DBS on motor control in Parkinson's patients.

Tuesday, December 11

1450-1457

Princesa Ballroom B-C (13)

6. Vim plus posterior subthalamic area DBS concurrently with Voa-Vop thalamotomy for Essential Tremor

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Introduction

Essential tremor is mainly a postural or kinetic tremor of the hands and sometimes the head. Because of some limitation and rather high morbidity of lesioning, deep brain stimulation (DBS) on ventralis intermedius (Vim) has been widely accepted procedures now on days. But the need for large target and complexity of tremor made us to find new targets.

In this report, we describe our surgical results of 15 patients of essential tremor treated with a new surgical technique, DBS on Vim plus posterior subthalamic area and thalamotomy on Voa-Vop in the unilateral thalamus for controlling essential tremor.

Materials and Methods

Between October, 2005 and February, 2007, we performed Vim plus posterior subthalamic area DBS concurrently with Voa-Vop thalamotomy for 15 patients who were diagnosed as severe proximal essential tremor and showed refractory to medications. Only one patient was female and the mean age was 56.4 (range 43 to 77). All procedures were performed unilaterally because all patients were right-handed, except for 3 patients, who were suffering from bilateral symptom. All procedures were performed under microelectrode recordings to select the target precisely, and author made two electrode contact (0,1) below the thalamus for subthalamic area stimulation. And additional small lesioning was made between Voa and Vop by moving 2mm anterior to Vim-Vop border.

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Results

More than 10 months were followed up (10 to 24 months), and mean improvement of tremor rating scale was 85.6%. All patients were right-handed, and the right side mean improvement was 87.7%. Voice tremor and head tremor of three patients was also improved.

Conclusion

DBS on Vim plus posterior subthalamic area concurrently with Voa-Vop thalamotomy showed good results for severe proximal form or axial type of essential tremor, and this combining procedures (targeting at two other site) are much more effective for controlling severe proximal tremor and subtle remnant tremor after single procedure.

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Learning Objectives:

1. To find more effective target for controlling the component of severe and complicated proximal tremor in essential tremor

Tuesday, December 11

1500-1507

Princesa Ballroom B-C (13)

7. Feasibility Study of an Implantable Cortical Stimulation System for Major Depression

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Introduction

Functional neuroimaging studies demonstrate abnormal regional glucose metabolism in subjects with major depressive disorder (MDD). Compared with control subjects, areas of ventral prefrontal cortex, such as subgenual cingulate, are relatively hypermetabolic in MDD, whereas dorsal regions such as left dorsolateral prefrontal cortex (DLPFC) are relatively hypometabolic.¹ High-frequency (>10Hz) rTMS can temporarily increase cerebral metabolism of targeted areas and when applied to the left DLPFC, has short-lived antidepressant effects.² Therefore, we examined an investigational implantable cortical stimulation (CS) system as a long-term method for stimulating left DLPFC in MDD.

Materials and Methods

After an observation phase of ≥ 8 weeks with stable psychotropic medication, 12 patients with treatment resistant MDD were implanted with an epidural CS system (*Renova™ DT*, Northstar Neuroscience, Seattle, WA). Patients were randomized to active or sham stimulation for 8 weeks, then active stimulation thereafter. Psychotropic medications were not changed unless clinically indicated. Safety outcomes were assessed. Efficacy assessment included Hamilton Depression Rating Scale (HDRS) and Global Assessment of Function (GAF). Baseline FDG-PET scans were obtained at baseline and post-stimulation.

Results



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At submission, 11 patients have completed the 8-week primary endpoint. A 12th patient is in baseline observation. At baseline, HDRS averaged 34.6 ± 5.3 , GAF averaged 41.4 ± 6.0 , failed antidepressant treatments averaged 9.6 ± 1.5 , and duration of current depressive episode averaged 7.3 ± 8.9 years. At the 8-week primary endpoint, active stimulation patients decreased in HDRS by $24 \pm 21\%$ whereas sham stimulation HDRS decreased by $3 \pm 17\%$. After 16 weeks of active stimulation for all patients, HDRS and GAF improvements doubled compared with 8 weeks, from 21% to 41% for HDRS and from 29% to 58% for GAF. There were no device related serious adverse events. PET data will be shown.

Conclusion

This feasibility study describes the first use of an epidural CS system targeting the left DLPFC in patients with MDD. Preliminary results indicate that CS may have a treatment effect that increases over time and exceeds that of sham stimulation.

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Learning Objectives:

1. Understanding the role of the DLPFC in the pathophysiology of MDD
2. Understanding the mechanisms of cortical electrical stimulation as a means of neuromodulation

Acknowledgements

This study was funded by Northstar Neuroscience, Inc., the manufacturer of the implanted stimulation device system.

Tuesday, December 11

1510-1517

Princesa Ballroom B-C (13)

8. Improvement of the upper limb movements of Parkinsonian patients after bilateral subthalamic DBS

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Introduction

Deep brain stimulation of the subthalamic nucleus (STN-DBS) reduces bradykinesia and rigidity in Parkinson's disease but its impact on fine motor functions of the upper extremity remains unclear. Some studies show an improvement on the grip force after DBS^{1,2,3,4} but none studied finer movement allowing patients to be more autonomous at home. Our goal was to establish if there was an improvement in upper extremity motor skills as well.

Materials and Methods

To assess improvement of the upper extremity movement, the following tests were performed on five (5) patients: Tempa^{5,6}, Cotnab and Finger-nose. These tests were done pre-operatively then 6 months after programming of their bilateral STN-DBS. Each of these tests was done for both hands and on-medication/on-stimulation.

Results

A better score was observed on finger-nose test for all patients due to improvement of the bradykinesia and alleviation of the rigidity. As suspected, the time taken to perform the Cotnab test was improved as well as the overall performance. Moreover, a significant improvement was seen for the Tempa test. Tempa test is divided into performing daily tasks and in lifting weights. The capability of lifting heavier weight during a

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longer time was improved as shown by other authors but more interestingly the capability of performing daily tasks was also improved.

Conclusion

Tempa and Cotnab tests are validated tests for elderly. These measure finer movement and general improvement of the upper limb allowing patients to be back to a more autonomous life. Our study shows that DBS treatment is not only good to alleviate bradykinesia and levodopa-induced dyskinesia but also allows patient to perform movements useful in their daily life increasing their autonomy. This study will be pursued with a larger population of STN-DBS patients and on a longer term follow-up to measure the consistency of these results.

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Learning Objectives:

1. To understand the impact of STN-DBS on fine motor skills
2. To measure the capability of DBS patients on performing daily activities.

Tuesday, December 11

1520-1527

Princesa Ballroom B-C (13)

9. Feasibility Study of an Implantable Cortical Stimulation System for Tinnitus

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Introduction

About 12 million US adults suffer from tinnitus severe enough to require medical treatment. Pharmacological approaches may improve emotional and psychological reaction to tinnitus but are less effective in improving tinnitus percept. Masking and retraining therapies provide mixed benefits. Recent evidence suggests aberrant cortical plasticity as an underlying mechanism.¹ Transcranial magnetic stimulation, epidural, and direct current stimulation of the auditory cortex can suppress tinnitus perception.^{2,3,4} This study explored the feasibility of an investigational epidural auditory cortex stimulation system for tinnitus suppression.

Materials and Methods

Patients with predominantly unilateral tinnitus for >1 year and scoring >33 on Tinnitus Reaction Questionnaire (TRQ) were implanted with an extradural electrode over the auditory cortex using fMRI targeting, connected to a subclavicular pulse generator (Northstar Neuroscience, Seattle, WA). Two-week periods of active and sham stimulation were alternated in blinded random sequence, followed by active stimulation with stimulation parameter adjustments to maximize tinnitus suppression. Safety outcomes were assessed.

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Results: At baseline, 8 patients had tinnitus for 15.8 ± 3.7 years, scored 83 ± 22 for loudness and 58 ± 23 for TRQ. No acute changes in tinnitus were noted within the 4-week crossover period but significant improvements were observed after several weeks of continuous stimulation. For responders, onset of relief was 2 to 27 weeks after stimulation initiation and took several more weeks (7 to over 24) for maximum effect. Thus far, 4 patients have lasting tinnitus suppression, and two others have experienced periods of total tinnitus suppression lasting 24-48 hours. At 6 months, 6 patients had significant improvements ($53 \pm 23\%$) in TRQ. There were no device related serious adverse events.

Conclusion

Electrical stimulation of the auditory cortex for the suppression of tinnitus is feasible and appears safe. After several week of CS, substantial and lasting suppression of tinnitus symptoms was observed in half of the patients. Additional studies will further characterize efficacy and best patient population.

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Acknowledgements

This study was funded by Northstar Neuroscience, Inc., the manufacturer of the implanted stimulation device system.

Learning Objectives

1. Understanding the role of posterior peri-sylvian regions in the pathophysiology of tinnitus
2. Understanding the mechanisms of cortical electrical stimulation as a means of neuromodulation

Tuesday, December 11

1530-1537

Princesa Ballroom B-C (13)

1. Reducing Mental Fatigue by Transcutaneous Electrical Acupoint Stimulation

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Introduction

Mental fatigue is a common symptom in neurology and psychology especially central nervous system, which can affect sense, memory, motion and emotion, resulting in reduced work efficiency, so the evaluation and countermeasure are becoming urgent problems to solve. Other than the usual countermeasures of drug, limited work load and proper rest, we have developed a method of transcutaneous electrical acupoint stimulation (TEAS) to release mental fatigue especially typical driving fatigue.

Materials and Methods

36 testees, 9 for daily fatigue and 26 for simulated driving fatigue, were measured and stimulated. The main tools to evaluate fatigue are time domain analysis and power spectrum analysis of EEG (Electroencephalogram). Assistant measures include subjective evaluation, driving performance evaluation and EOG (Electro-Oculogram) evaluation. TEAS is researched for therapy of fatigue, in which three

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acupoints of Fengchi, Hegu and Neiguan are used for electrical stimulation. The stimulation parameters are: amplitudes of 3-5mA, rates of 2Hz or 2Hz/100Hz, and pulse widths of 600_s for 2Hz and 200_s for 100Hz.

Results

For most testees, fatigue is lessened after TEAS in daily fatigue experiment and simulated driving fatigue experiments. The changes in EEG are the decreases of fascicled _ waves and large-amplitude _ waves. And the values of average power spectral density of _ band, _ band, _ band and _ band are reduced as well. The changes of assistant measures are consistent with EEG. Subjective feeling of fatigue is weaker, error of driving performance is less and the eye blinking tends to be normal. TEAS has positive effect on restraining fatigue for most testees, but the effects are negligible or even negative for some testees.

Table 1. Ratios of G values (Average Power Spectral Densities) in _ , _ , _ EEG bands for Testee 1# (F: Fatigue, S: After Stimulation)

Brain Region	$\frac{G_S(\theta)}{G_F(\theta)}$	$\frac{G_S(\alpha)}{G_F(\alpha)}$	$\frac{G_S(\beta)}{G_F(\beta)}$	Brain Region	$\frac{G_S(\theta)}{G_F(\theta)}$	$\frac{G_S(\alpha)}{G_F(\alpha)}$	$\frac{G_S(\beta)}{G_F(\beta)}$
F3	0.556	0.540	0.584	P3	0.769	0.576	0.792
Fz	0.884	0.654	0.702	Pz	0.891	0.553	0.838
F4	0.707	0.543	0.584	P4	0.933	0.567	0.902
C3	0.691	0.615	0.811	O1	0.772	0.607	0.626
Cz	0.815	0.612	0.790	Oz	0.449	0.502	0.442
C4	0.671	0.537	0.758	O2	0.593	0.598	0.614

Conclusion

TEAS can reduce mental fatigue for most testees, and provides an effective approach to fatigue therapy. The mode and parameters of the electrical stimulation which are not suitable for all testees need to be studied and improved.

Acknowledgements

This study has been supported by National High Technology R&D Program of China (863 program) (Grant No.2006AA02Z4E9) and National Key Technology R&D Program of China (Grant No.2006BAI03A18).

Learning Objectives:

1. TEAS is an effective method to reduce mental fatigue.
2. EEG is important evidence for fatigue evaluation and TEAS effectiveness.
3. EEG can be used for feedback for treatment such as TEAS.

Tuesday, December 11

1540-1547

Princesa Ballroom B-C (13)

2. Computer modeling of Motor Cortex Stimulation: Effects of Anodal, Cathodal and Bipolar Stimulation

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Introduction

Motor cortex stimulation (MCS) is a promising clinical technique for treatment of chronic pain. However, optimization of the therapeutic efficacy is hampered since it is not known how electrically activated neural

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

structures in the motor cortex can induce pain relief. Furthermore, multiple neural elements are present in the motor cortex such as cell bodies, dendrites and axons which are parallel or perpendicular to the cortical layers. Which of these neural elements are immediately excited by the electrical pulses in MCS depends on positioning of anodal and cathodal electrodes and stimulation parameters. A proper insight on these effects would be useful for peroperative decision making on electrode positioning and for the interpretation of stimulation results after implantation. Computational modeling studies can help to identify the effects of electrical stimulation on cortical neural tissue, elucidate mechanisms of action and ultimately to optimize the therapy.

Methods

The activation of neural elements in the precentral gyrus and in the anterior wall and lip of the central sulcus was studied by (1) calculating the stimulus-induced electrical field using a realistic 3D volume conductor model, and (2) simulation of the response of neural elements using compartmental neuron models including the axon, soma and dendritic trunk.

Results

While neural elements perpendicular to the electrode surface are preferentially excited by anodal stimulation, cathodal stimulation excites those with a direction component parallel to its surface. When stimulating bipolarly, the excitation of neural elements parallel to the bipole axis is additionally facilitated. The polarity of the contact over the precentral gyrus determines the predominant response. Inclusion of the soma-dendritic model generally reduces the excitation threshold as compared to simple axon model.

Conclusions

Electrode polarity and electrode position over the precentral gyrus and central sulcus have a large and distinct influence on the response of cortical neural elements to stimuli.

Learning Objectives

1. Which neural elements are activated by Motor Cortex Stimulation?
2. What is the effect of MCS electrode positioning on neural activation?
3. What is the role of Anodal, Cathodal and Bipolar stimulation?

Tuesday, December 11

1500-1557

Princesa Ballroom B-C (13)

3. Neuromodulation on Inferior Thalamic Peduncle in Five Patients with Obsessive Compulsive Disorder Treated with Neuromodulation

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Introduction

Deep brain stimulation (DBS) has been used in the treatment of refractory obsessive compulsive disorder (OCD). Inferior thalamic peduncle is a bundle of fibers that link non-specific thalamic system with orbitofrontal cortex. Experimental, neurosurgical and PET scan image suggest that this system could be useful in treatment of OCD symptoms.

Patients and Methods

One study was performed in five patients with OCD refractory to conventional treatments. Our principal objective was to determinate safety and effectiveness of DBS of inferior thalamic peduncle (ITP). Bilateral stereotactic implantation of tetra-polar electrodes was aimed at ITP and corroborated by electrophysiological responses and magnetic resonance imaging (MRI). All patients were in OFF stimulation 1 month after implantation. In ON period, parameters were set at 5 volts, 450 microsecond of width pulse, 130 Hertz in bipolar and continuous mode. Clinical changes were evaluated every 3 months for 12 months by means of Yale-Brown Obsessive Compulsive Scale (YBOC-S) and Global Assessment Functioning Scale (GAF). Statistical significance was assessed by Friedman and Wilcoxon statistical test.

Results



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By the end of the study Y-BOCS score decreased 20 points ($p < 0.001$), and GAF score improved from 20 to 70% ($p < 0.0001$). Neuropsychological battery showed no changes and there were no side effects in the chronic period.

Conclusions

We conclude that ITP stimulation is a safe and maybe effective alternative in treatment of those OCD cases refractory to conventional treatments.

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Learning Objectives

1. Patho-physiology in obsessive compulsive disorder
2. Advantages of neuromodulation in psychiatric disorders
3. Safety of neuromodulation procedures in new target

Tuesday, December 11

1630-1637

Princesa Ballroom B-C (13)

4. Effects of changes in patients posture on energy requirement for SCS

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Introduction

Over the last few decades, spinal cord stimulation (SCS) has become one of the main treatments in the therapeutic arsenal available to pain treatment units. New stimulation systems have been developed and the indications of neurostimulation have been expanded. The premises for a successful technique remain the same; good patient selection, good surgical technique and good management of electrical parameters when programming. The primary objective of the study was to determine the relationship between energy requirement (E) elicited by changes in patients posture (1,2). The postures analyzed were: supine (S), sitting (SI), standing (ST) and walking (W). The primary objective of the study was to determine the relationship between patients posture and energy requirement (E).

Materials and Methods

A study was carried out in 70 patients with chronic intractable pain implanted a neurostimulation system between January 2000 and March 2006. We define the perception threshold (Tp); the discomfort threshold (Td); and the therapeutic threshold (Tt). The amplitude of perception was measured in mA. With the resulting data, the therapeutic range (TR) was determined (3). After performing all measurements with the patient in the ST position, the neurostimulation system was shut off and the patient maintained in the other

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

position for 5 minutes before performing the measurements. The variables R and E were compared by age groups, sex, implant duration, and whether the time since implant placement. Patients were divided into groups according to whether the location of the implanted electrodes was cervical, thoracic. The full analysis by age, sex and implant duration was performed in the cervical and thoracic implant groups.

Results

The analysis of the TR reflects a statistical difference, in the global group, between the positions of S and ST ($p = 0.03$) and in S and W ($p = 0.02$). At thoracic level differences between all the positions except between ST and W ($p = 0.95$) and in SI and S are appraised ($p = 0.73$). At cervical level, statistically significant differences are not appraised. In the analysis of the E, as much at cervical level as at thoracic level, a statistically significant difference with respect to position S is appraised, in both cases the energy necessity to cause a correct stimulation is smaller ($p < 0.001$), as the group of global form happens when analyzing. In the analysis when comparing the electrodes implanted at cervical and thoracic level difference ($p = 0.04$) in ST and SI ($p = 0.27$) without differences in neither ST nor W is reflected. In the analysis of the E with respect to sex and age are not statistical differences for any of the values and in any position. In the study time of evolution, greater or smaller of 6 months, differences are not appraised either.

Conclusion

The systems of constant current do not have a "rapidity of reflections", at the present time, sufficient to vary the voltage of stimulation with the sudden changes of the position of the patient.

References

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3. Barolat G. Epidural spinal cord stimulation: Anatomical and electrical properties of the intraspinal structures relevant to spinal cord stimulation and clinical correlations. *Neuromodulation* 1998; 2; 63-71.

Learning Objectives

1. The factor that influences more in the profit of an effective stimulation seems to be the distance of the system to the CSF (6). Other factors that influence in the good stimulation are the different excitabilidad from the different nervous structures, the direction of the electrode and the pattern of stimulation.
2. These results also seem to reduce the importance of whether voltage dependent or constant current systems are used.
3. We need have better information systems that permit us controlling the outcomes in a more effective and predictive way.

Tuesday, December 11

1640-1647

Princesa Ballroom B-C (13)

5. Initial Evaluation of Triple-Array Leads for Spinal Cord Stimulation

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Introduction

Paddle leads with three parallel electrode arrays (i.e., tripolar leads) are increasingly used for spinal cord stimulation. Preliminary data has suggested that tripolar leads can provide broad paresthesia coverage to patients with concurrent low back and low extremity pain.¹

In this poster, we present the initial outcomes of chronic pain patients who were treated with spinal cord stimulation using an anatomically shaped tripolar lead.

Materials and Methods



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Data was collected retrospectively on (n to be determined) patients suffering from refractory low back and leg pain who had been implanted with tripolar leads. The data included information on pain relief, paresthesia coverage, and stimulation programming.

The tripolar lead had a middle array of six electrodes flanked by two outside arrays of five electrodes each (Fig. 1). The electrodes could be individually controlled to direct the stimulation over the dorsal columns. In cross-section, the lead was contoured to help it conform to the shape of the dura.

Results

All patients had been diagnosed with failed back surgery syndrome and had pain in the low back, buttocks, and/or legs (Fig. 2). The majority of patients had axial back pain that extended to the L4 vertebral level (Fig. 3). At an average of (info pending) months post-implantation, the patients reported substantial declines in pain (Fig. 4). All but one patient had complete coverage of their pain topography. Programming parameters for the patients varied, as did the location of their electrode combinations on the lead (Fig. 5).

Conclusion

In this preliminary survey, tripolar leads provided broad paresthesia coverage to patients with low back and lower extremity pain, with pain relief extending as high as the L4 dermatomes.

References

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Acknowledgements

This research was funded by Advanced Neuromodulation Systems.

Learning Objectives:

1. Increase knowledge of tripolar leads used for spinal cord stimulation
2. Review initial data on patients who have used tripolar leads
3. Understand how tripolar leads may affect patient outcomes

Tuesday, December 11

1650-1657

Princesa Ballroom B-C (13)

6. Feasibility of Absolute Migration Detection Using Electrical Measures in Spinal Cord Stimulation (SCS) Leads

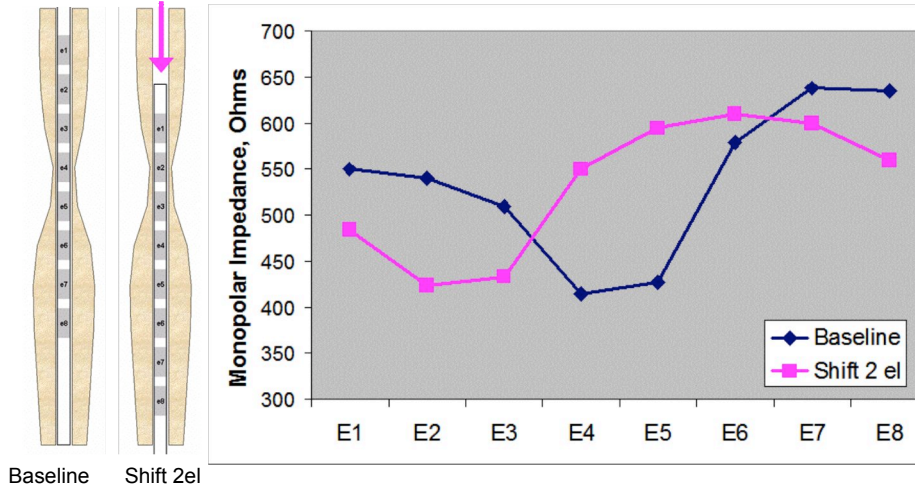
Kerry Bradley, MD, Boston Scientific Corporation, Valencia, CA
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Introduction

We investigated a new technique for determining the spatial position of implanted SCS leads without radiographic imaging. The method uses electrical monopolar contact impedance (Z) measured in vivo, which is sensitive to the characteristics of the tissue adjacent to the contacts. The inhomogeneity of the surrounding tissue creates a variable impedance profile along the array, which can be used as reference data for absolute position.



ORAL PRESENTATION ABSTRACTS AND SCHEDULE



Methods

Two caprines (goats), each implanted with an SCS system (Precision™ implantable pulse generator (IPG); 2 Linear™ octopolar leads) were studied after > 4 weeks chronic implant. During explant, the leads were accessed at the spinal exit site while still connected to the IPG. Z was measured during a “pull-test:” a fluoroscope was positioned over the thorax of the animal. One lead was pulled caudally, while the other remained static. The pulled lead was repositioned four times. After each reposition, Z was measured and the fluoroscope image was printed. Afterwards, the fluoro printouts were scanned and brought into a quantitative imaging software application. The (x, y) position of each contact on the printout was measured and the impedance along the array was used to create a one-dimensional “map.” Pearson’s correlation coefficient was used to quantify the level of agreement between the fluoro image-based model and the measured Z.

Results

Median monopolar impedances in each animal were: #1 = 520 (410-638) Ohms; #2 = 685 (530-848) Ohms. In both animals, the pull test shifted one lead by approximately 11 mm. The correlation coefficient between the fluoro image-based model and the actual Z measurements ranged between 0.95 – 0.99.

Conclusions

An electrical method has been developed for estimating the absolute longitudinal position of a percutaneous SCS lead within the epidural space. This “electric fluoroscope” might be employed to track lead migration in an implanted SCS system.

Acknowledgements

This work was fully funded and supported by Boston Scientific Corporation.

Tuesday, December 11
1700-1707
Princesa Ballroom B-C (13)

7. Prospective, multi-centered study to evaluate the safety and effectiveness of Genesis® Implantable Pulse Generator in combination with percutaneous leads for the management of chronic pain of the trunk and/or limbs.

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Introduction

Spinal Cord Stimulation (SCS) is a proven treatment for chronic pain, but there is still a need for additional high-quality prospective clinical study data. The final results of a prospective multi-centered study of the Genesis IPG (ANS; Plano, TX) are presented.



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Materials and Methods

This study was designed as a prospective, multi-centered, 3 month post-implantation study. After informed consent was obtained, patients were screened according to the inclusion/exclusion criteria. The primary endpoint was to observe if there is pain reduction as demonstrated by the Visual Analog Scale (VAS) at the 3 month visit. Data were also collected on overall pain relief, verbal percentage of pain relief, satisfaction, quality of life, change in medication usage and adverse events.

Results

The mean reduction of VAS from baseline to 3 months was 58.6%. The mean percentage of patient reported pain relief as "Excellent" or "Good" was 67.3% and 77.3% respectively. The majority of patients (81.8%) reported decreased medication use since implant. Also, 90.9% of patients reported being "Very Satisfied" or "Satisfied" with SCS therapy and 84.1% of patients reported quality of life as "Greatly Improved" or "Improved" since implant. Out of 51 patients implanted, there were 4 serious Adverse Events, 2 of which were not related to therapy, one patient reported a serious infection and one patient reported serious pain and/or redness at the implant site.

Conclusions

The Genesis[®] IPG in combination with the percutaneous leads offers a safe and effective treatment option in the management of chronic intractable pain.

Acknowledgements

The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:

1. Describe results of spinal cord stimulation using percutaneous leads in treatment of chronic pain.
2. Discuss low rate of surgical and treatment-related complications of spinal cord stimulation.
3. Discuss high level of patient satisfaction and quality of life related to spinal cord stimulation approach.

Tuesday, December 11

1710-1717

Princesa Ballroom B-C (13)

8. Differential effects of spinal cord stimulation are achieved with three lead patterns

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Introduction

Implantable neurostimulation systems drive up to 16 contacts and can support multiple columns of electrodes for spinal cord stimulation (SCS). A wide array of percutaneous leads are currently available that provide varying degrees of longitudinal coverage along the spinal cord. Three-column patterns with different electrode spacings can be studied using computer models by determining the effect of a particular electrode configuration on fiber selectivity and energy consumption.

Materials and Methods

Using a finite element program, the electric field was generated for three configurations with a midline cathode: an "X" pattern with 4 anodes placed in the four corners diagonal to the cathode, a "Y" pattern with 2 anodes above and 1 anode below the cathode, and a "+" pattern with an anode above, below, and 2 anodes transverse to the cathode. Three variations of these configurations were modeled using a 4-8-4 array: two standard-spaced (9 mm center-center), four-electrode leads flanking a standard (9 mm center-center), compact (7 mm center-center), or subcompact (4.5 mm center-center) eight electrode lead. Axon models were used to calculate dorsal column (DC) and dorsal root (DR) fiber activation thresholds. The energy per pulse and the area within the dorsal columns activated by the stimulation was determined using these models.

Results

Neuron activation areas revealed slight differences with each modeled configuration. When only one cathode in the midline was used ("X" pattern), there was a negligible effect on DC fiber selectivity and on

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energy consumption. For the “Y” and “+” patterns, the lead with the smaller electrode center-center spacing resulted in the greatest selectivity of DC vs. DR fibers. However, this benefit was obtained at the expense of a higher energy demand.

Conclusion

Multiple three-lead configurations for SCS can be created using a bifurcated extension that offers flexibility and new patterns for paresthesia coverage.

Acknowledgements

This research was funded by Medtronic

Learning Objectives:

1. Describe the effect of X, Y and + patterns on DC fiber selectivity and energy consumption.

Tuesday, December 11

1720-1727

Princesa Ballroom B-C (13)

9. Dorsal Column Selectivity in Pulse Width (PW) Programming of Spinal Cord Stimulation (SCS): Computation model for the “Sacral Shift” (A Mathematical Application)

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Brad Hershey, M.S., Kerry Bradley, M.S., Michael Moffitt, Ph.D., Dave Peterson, Ph.D., Thomas Yearwood, M.D., Ph.D.

Introduction: In a recent SCS clinical study, the focus of paresthesia was observed to shift caudally as PW was increased in 35% of patients. A recently developed computational model of SCS with realistic fiber size, density, and distribution was used to understand the effect of PW on neural activation in SCS.

Methods: The mathematical model of SCS consisted of a volume conductor model based on human morphometric data¹, and non-linear myelinated fiber models² with a range of sizes and densities observed in human histological studies³. Fibers corresponding to caudal dermatomes were assumed to be distributed in the medial dorsal column (DC) while rostral dermatomes corresponded to the lateral DC³ (Fig 1A). Four different pulse widths (60, 210, 450 and 1000 μ s) were applied to the model (guarded cathode configuration; 8 mm anode-cathode spacing) and distribution of stimulated fibers of several diameters were computed. The location of the focus of paresthesia for each pulse width was estimated by computing the total number of stimulated fibers from the medial (MedF) and lateral (LatF) regions (Fig 1B) and their ratio (LatF/MedF) (Fig 1C).

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

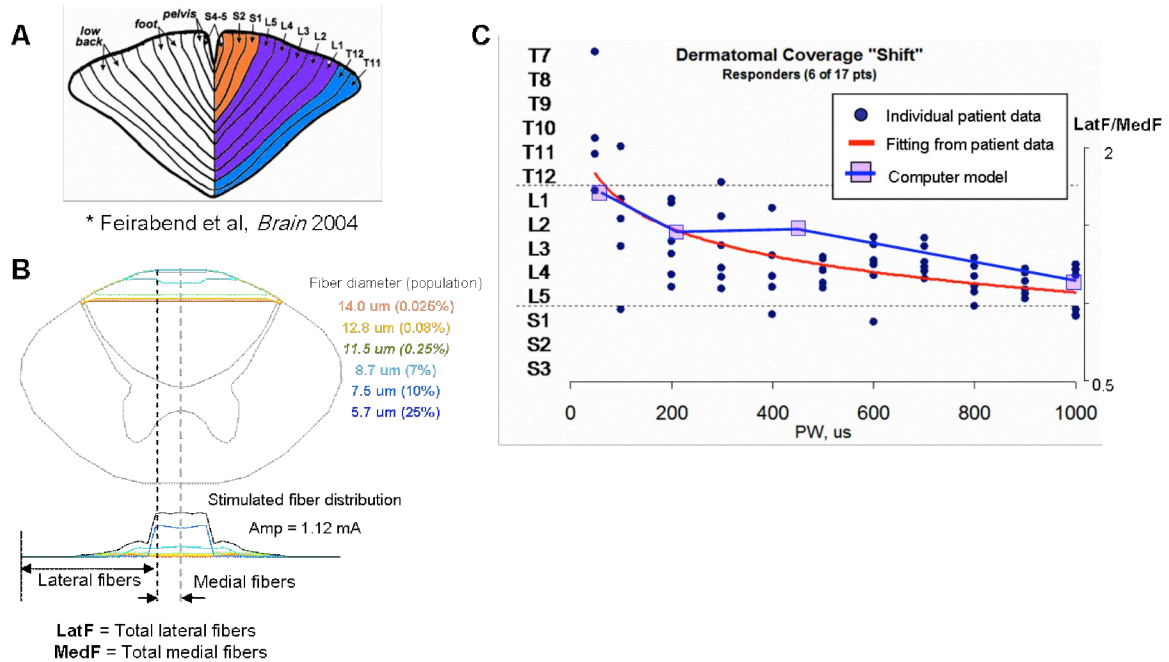


Figure 1. (A) Dermatomes in DC. (B) Model-predicted stimulated fiber distribution (PW = 1000 μs), (C) Fiber ratio (LatF/MedF) changes with PW consistent with clinical data.

Results: The fiber ratio was smaller for wide PW than short PW predicting that wide PW will recruit more medial fibers than short PW. If medial fibers map to caudal dermatomes, increasing PW may correspond to shifting the paresthesia focus caudally, consistent with the clinically-observed 'sacral shift.'

Conclusion: Predictions of the effect of PW in SCS with a mathematical model incorporating realistic fiber size, density, and distributions, showed good agreement with clinical data.

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3. McIntyre et al., Modeling the excitability of mammalian nerve fibers: influence of afterpotentials on the recovery cycle, *J Neurophysiol*. 2002. 87(2):995-1006

Learning Objectives:

1. To understand that the focus of paresthesia shifted caudally as PW was increased.
2. To develop computational model of SCS with realistic fiber size, density, and distribution
3. To understand the effect of PW in spinal cord stimulation

Tuesday, December 11

1730-1737

Princesa Ballroom B-C (13)

10. Dorsal Column Selectivity in Pulse Width (PW) Programming of Spinal Cord Stimulators (SCS): the "Sacral Shift"

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Comprehensive Pain and Rehabilitation, Pascagoula, MS, Daphne, AL

Brad Hershey MS, Kerry Bradley MS

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Introduction

To understand the effect of PW programming in SCS, we prospectively evaluated the paresthesia coverage for a wide range of programmed PW settings.

Methods

Subjects were enrolled in whom chronic pain of the back and/or lower extremities was treated with Precision SCS and dual Linear™ 8-contact leads (Boston Scientific) placed between T7-T9. PW programming utilizing the patient's preferred existing program was performed during the first 6 months post-implant. For each PW (range: 50-1000µs, randomized order, blinded patient) at a maximum comfortable mA setting, patients drew areas of paresthesia on a human figure on a tablet PC, with electronic drawing capture. To analyze the selectivity of paresthesia generation at different PW settings, we divided the body figure into classic dermatomal segments defined by a Netter drawing standard. For each patient, we calculated the number of paresthesia pixels in all dermatomal segments at each PW. From this dermatomal distribution of paresthesia (Figure 1), the median was defined as the 'focus' of paresthesia for that PW setting. For all patients, we plotted the focus of paresthesia vs. PW and applied ANOVA to responders.

Results

Seventeen patients have been studied. Of these, one third (N=6) were characterized as responders, as they displayed a significant shift of the focus of paresthesia with increasing PW (Figure 2), typically from low-thoracic/high lumbar dermatomes at low PW, to low-lumbar/high-sacral dermatomes at higher PW: a "sacral shift." Non-responders had little shift of paresthesia focus, since they achieved low-lumbar/high-sacral dermatomal coverage at all PW settings.

Conclusions

We have demonstrated that PW programming provides 'selectivity' for dorsal column fiber activation. In patients who achieve only thoracic/lumbar coverage at low PW settings, higher PW programming can shift the paresthesia caudally, presumably by activating more midline fibers in the dorsal columns. In effect, PW can be used to 'steer' the paresthesia focus on the body.

Acknowledgements

This work was fully funded and supported by Boston Scientific Corporation.

Tuesday, December 11

1740-1747

Princesa Ballroom B-C (13)

11. Hybrid Spinal Cord Stimulator Experience: First 25 Patients Using Leads from One Manufacturer with IPG from Another

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Introduction

Patients with one type of spinal cord stimulator system (SCS) have been at a disadvantage when a component fails and needs replacement. Until the advent of another system which is adaptable to the electrode leads of another manufacturer the only options were either to replace the failed IPG or receiver of the original system, or to replace all components of the implanted system with a full system from another manufacturer. (1)

We present our experience over the first 25 patients who had functional leads, but non-functional or gave sub-optimal outcome in pain relief. (Table 1)

Patient Demographics

Gender	Age	Time of Treatment (Months)	Lead Location	Diagnosis
Male 8	Minimum 28	Minimum 5	Cervical 3	CRPS 12
Female 17	Maximum 74	Maximum 28	Thoracic 14	FBSS 10
			Lumbar 7	IC 1
			Sacral 1	L5/S1 DNR 2
Total 25	Median 53	Median 14	Total 25	Total 25

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Materials and Methods

Full informed consent with explanation of this “off-label” use was discussed and accepted.

In patients with functioning leads (Octrode, Quatrode or Lamitrode leads. Advanced Neuromodulation Systems (ANS), Plano, TX) we utilized the existing leads with an IPG from another manufacturer (Precision IPG, Advanced Bionics (AB), Valencia, CA.) Patients were trialed intra-operatively with the existing ANS leads with the AB Precision IPG.

To prevent damage to either component, an extension cable from ANS was connected to the proximal lead contacts. An AB extension cable attached to the AB Precision IPG and the 2 extensions were connected and tested.

Results

All 25 patients obtained excellent outcomes. There were few cases when a minority of contacts did not function. The paresthesia coverage was the same or better in paresthesia coverage and pain relief compared to their original implant. The impedance measurements using both systems in tandem were lower than expected. Each patient expressed better paresthesia sensations and decrease in pain level than the original system. (Table 2)

Patient Reported Comments

Better Pain Relief	25	
Worse Pain relief	0	
Would Do Again	24	
Subjective Decrease in Pain after Hybrid System	Mean 76.40%	Range 50 to 100%
Deeper Stimulation	72%	

Conclusion

Replacing an SCS system IPG or receiver with electrode contacts of the original system with a different power source can be successful.

References

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Acknowledgements

No funding sources or other contributors to the research in this abstract were used.

Figure and Table Legend

- (1) Table 1: Patient demographics
- (2) Table 2: Patient reported comments

Learning Objectives:

1. A minor procedure can prevent total SCS system replacement.
2. Mixing of two separate SCS systems can be accomplished.
3. Hybrid system outcomes are successful if proper component and procedures are utilized.

Tuesday, December 11

1750-1757

Princesa Ballroom B-C (13)

12. Management of Interstitial Cystitis Related Pain Using Antegrade SCS Lead

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ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Introduction

Neuromodulation will continue to be a useful therapeutic modality in interstitial cystitis. Application of antegrade spinal cord stimulator lead at the level of T7 is a novel alternative treatment for pelvic pain secondary to interstitial cystitis.

Materials and Methods

We present a case report of a male with pelvic pain secondary to interstitial cystitis that was successfully treated with a spinal cord stimulator lead placed at the level of the vertebral body of T7. The trial was conducted for one week using an Advanced Bionics Linear eight contact lead (Advanced Bionics Valencia, California). The patient had significant pain improvement (> 70% reduction in his VAS of pain). After the trial he underwent surgical implantation of the lead. Excellent coverage of the painful pelvic area achieved in the immediate postoperative period and in one week after the implantation and after 12 months of follow-up.

Conclusion

This case demonstrates adequate coverage of pelvic pain by antegrade dorsal column stimulation. The implantation of sacral nerve stimulator leads in the treatment of pelvic pain using retrograde approach had been associated with, in addition to technical difficulty during placement, increased likelihood of lead lateral migration. Also, due to the relative mobility of the conus and the large fiber afferents from the pelvis, stimulation at the upper lumbar and lower thoracic levels in attempt to cover pelvic pain, frequently produces inconsistent and undesirable paresthesia in adjacent regions. One of the possible mechanisms for the pain relief may involve modulation and interruption of the midline relatively deep dorsal column pathways that mediate the perception of pelvic pain secondary to interstitial cystitis. Patients may have responded well to electrical stimulation by tightly spaced electrode as in the compact lead used in this case report. These leads are known to drive stimulation deeper into the dorsal spinal column where these pathways may be located. That might explain adequate coverage that can be achieved by modulating these pathways that are deep into the dorsal column at the midthoracic level.

References

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Janicki TI. Chronic pelvic pain as a form of complex regional pain syndrome. *Clin Obstet Gynecol* 2003;46:797–803.

Learning Objectives:

1. Neuroanatomy of the Pelvis
2. Pathophysiology of Interstitial Cystitis
3. Neuromodulation of the Dorsal Column

Tuesday, December 11

1630-1637

Marquesa III-IV (16)

13. Safety and effectiveness of C-Series leads in combination with the Genesis® XP Implantable Pulse Generator for the management of chronic pain of the trunk and/or limbs.

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Introduction

The novel C-Series Lamitrode® leads (ANS; Plano, TX) mimic the curve of the epidural space and are designed to direct stimulation toward the spinal cord and to minimize unwanted stimulation in the posterior epidural space. Presented are data from a prospective multi-centered study of the Genesis® XP IPG (ANS; Plano, TX) for the management of chronic pain.

Materials and Methods

This study was designed as a prospective, multi-centered, 3 month post implantation study. After Informed Consent was obtained, patients were screened according to the inclusion/exclusion criteria. The primary endpoint was to observe if there was pain reduction by using the Visual Analog Scale (VAS) at the 3 month visit. Data was also collected on overall pain relief, verbal percentage of pain relief, satisfaction, quality of life, change in medication usage and adverse events.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Results

Detailed results will be presented.

Conclusions

The C-Series Lamitrode® leads offer a safe and effective treatment for chronic pain and may help decrease the chance for lead migration.

Acknowledgements

The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:

1. Recognize the advantages of a curved surgical lead.
2. Understand the implications of lead migration rates.

Tuesday, December 11

1640-1647

Marquesa III-IV (16)

14. Successful Treatment of Chronic Axial Low Back Pain and Bilateral Radicular Leg Pain in Two Cases of Failed Back Syndrome (FBSS) and Lumbar Spondilosis with a New Technique of Spinal Cord Stimulation (SCS) : The “Electical Fractionalization”

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A. Dario MD

Introduction

The purpose of this communication is to highlight the therapeutic success achieved in two young patients (54 and 36 years old) with low back and radicular pain due to lumbar laminectomy (fbss) and lumbar spondilosis. Both patients had undergone SCS (dual quadripolar lead) at D8 level and both patients experienced partial leg pain relief but almost no low back pain relief (1,2,3).

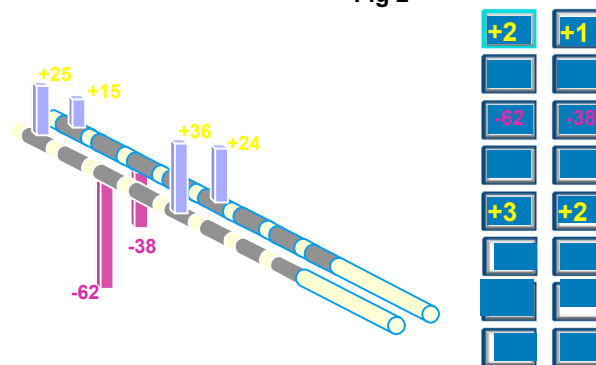
Materials and Methods

A new kind of spinal cord stimulation delivery, named “current fractionalization” was proposed to both patients. After written informed consensus gaining, the procedure took place. In both patients a new surgical paddle lead with closely-spaced contacts mod. Artisan 2x8 (Boston Scientific Inc, Valencia, CA), was positioned in the epidural space on the midline at T9-T8 level (fig 1), and then connected with tunneled subcutaneous extension at the external Pulse Generator for trial phase.

Fig 1



Fig 2



1. A surgical paddle 2x8 Artisan implanted (x-Ray view)
2. “Current Fractionalization”: a spatial schematization

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Results

Both cases a complete paresthesia coverage of the painful area was achieved through two tailored stimulation programs based on “constant current control and fractionalization” technology (fig 2). A nervous system resistance independent stimulation control was also achieved.

After two weeks the best stimulation effect was reached: excellent lumbar and radicular pain relief (VAS from 10 to 3 in first patient and from 10 to 2 in second one), performance improvement measured as standing position time and pain free walking.

Precision™ (Boston Scientific Inc.) fully implantable and rechargeable neurostimulation system was implanted in both patients after 45 days of trial stimulation.

Conclusion

Precision™ (Boston Scientific Inc.) fully implantable and rechargeable neurostimulation system and Artisan 2x8 paddle lead (Boston Scientific Inc.) may be properly used in Axial Low Back Pain thanks to the broader involvement of neural cordonal tissue, compared to traditional SCS technology (4,5).

We indicate the use of this new technology in young patients, in alternative to traditional surgical treatments or in the cases of failure of traditional SCS.

Reference

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Acknowledgements

Boston Scientific Inc., Valencia, CA, USA.

Learning Objectives:

1. Divulgation a new system of neurostimulation. (*Indipendentr current control systems*)
2. Possible application of neurostimulation in young non operable patients in alternative at the surgical way.
3. Improve our knowledge in neuromodulation field.

Tuesday, December 11

1650-1657

Marquesa III-IV (16)

15. Percutaneous tripole array programming and stimulation coverage in a patient with failed back surgery syndrome implanted with an Eon® Rechargeable IPG and three percutaneous leads: a case-study.

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Jala Zinck, BA

Introduction

Transverse tripole programming allows clinicians to possibly increase back stimulation field by avoiding stimulation in the dorsal roots thereby controlling boundaries of the stimulation field. A case-study is presented to illustrate the benefits of transverse tripole programming.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Materials and Methods

Data is being collected from an ongoing clinical research study being conducted with patients implanted with the Eon[®] Neurostimulation System (ANS; Plano, TX). This study is a prospective, multi-centered, 2-year post-initial programming study. After informed consent is obtained, the patients are evaluated prior to the system implant. Patients then return for evaluation at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years post implant. The following parameters are evaluated during the study: patient reported pain relief, patient reported satisfaction level, patient reported area of paresthesia coverage of their painful area, lead placement, device programming, patient quality of life, and patient disability.

Results

The patient's baseline pain peaked at 5 inches above the iliac crest along the spine descending to 2 inches above the iliac crest on the right and left side of the back. At the one month visit the patient had two programs, a transverse tripole (TT) and a guarded cathode on the midline lead (GC). The GC program provided stimulation up to the iliac crest on a back grid and only through the upper buttocks on an anatomical chart. The TT program gave stimulation up to 6 inches at center, 1 inch at left, and 4 inches at right back above the iliac crest. The patient also indicated stimulation in the lower axial back on the anatomical chart. The GC program was only able to provide 50% coverage of the initial pain region, whereas the TT program provided 93.3% coverage. Furthermore, the patient reported a 100% pain relief in the back at the one month visit.

Conclusion

This case-study illustrates a possible programming option with transverse tripole programming for increasing stimulation coverage. Further investigation is needed into transverse tripole programming.

Acknowledgements

The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:

1. Understand the difficulties in stimulation coverage of low back pain.
2. Recognize the advantages of transverse tripolar programming.

Tuesday, December 11

1700-1707

Marquesa III-IV (16)

16. Cost Minimisation in Spinal Cord Stimulation

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Dr Declan O'Keeffe, MD, FCARCSI, Dr Oleg Ilyinski MB, FCARCSI, Dr Abdul AlMajadi MB, FCARCSI, Dr Aamir Zuberi MB, FCARCSI

Introduction: To assess the healthcare utilization of patients with intractable chronic neuropathic pain treated with spinal cord stimulation and to provide a cost-benefit analysis of rechargeable versus non-rechargeable Implantable Pulse Generators (IPG's).

Materials and Methods: The case records of 50 consecutive patients who received spinal cord stimulation at St Vincent's University Hospital, Dublin were reviewed retrospectively. Implanted pulse generators (IPG) were of two types, rechargeable (ANS) and non-rechargeable (Advanced Bionic).

Data on patient satisfaction, healthcare resource utilisation, stimulation parameters, IPG survival time, replacement intervals and ancillary peri-operative costs was obtained and subjected to cost-benefit / minimisation analysis.

Results: The mean patient age was 45 years. Both systems were associated with effective pain control and reduced health care resource and medication utilisation. The mean non-rechargeable IPG survival was 29.7 months with total of 19 non-rechargeable IPG's requiring replacement.

Conclusion: Despite higher initial costs relative to non-rechargeable systems, rechargeable IPG's are cost neutral at 36 months.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

References

1. Mekhail NA, Aeschbach A, Stanton-Hicks M. Cost benefit analysis of neurostimulation for chronic pain. Clin J Pain 2004;20:462-8.

Learning Objectives:

1. Rechargeable IPG should be considered in preference to non-rechargeable if the requirement for SCS is considered to be in excess of 36 months duration

Tuesday, December 11
1710-1717

Marquesa III-IV (16)

17. Cost-Utility and Cost-Effectiveness of SCS in Patients with FBSS Compared to Conventional Medical Management: the PRECISE STUDY

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Lavano, P. Poli, G. Fortini, L. Demartini, P. Cisotto, E. De Simone, V. Menardo, M. Meglio, A. Costantini

Introduction

Several publications clearly indicate effectiveness and safety of Spinal Cord Stimulation (SCS) in Failed Back Surgery Syndrome (FBSS) treatment but no Italian economic evaluation study has been developed yet.

PRECISE study was developed to conduct a cost-effectiveness analysis of SCS treatment versus Conventional Medical Treatment (CMM).

Materials and Methods

The PRECISE Trial is an observational, pre-versus-post, multi-centre study. 80 patients will be enrolled and followed-up for two years by 9 Italian centers (3 Neurosurgical Units and 6 Pain Units). To evaluate Incremental Cost per QALY and Incremental Cost per Pain Reduction of SCS compared to CMM an ad-hoc questionnaire has been developed by physicians and health economists. Data for health care economic evaluation (hospitalizations, specialist visits, diagnostic tests, drugs, rehabilitation, prosthesis), non health care costs (working day loss, care-giver, travel expenses) and quality of life (SF-36 and EQ-5D questionnaires) is being collected. Effectiveness will be assessed with clinical (NRS/VAS), and functional (Oswestry questionnaire) measurements. Data is being collected retrospectively for 12 months before lead implant, prospectively for 1 month after lead implant (pre-implant prospective evaluation phase) and for 24 months after SCS treatment starts (post-implant prospective evaluation phase).

The study started on May 2005 and with the actual enrollment trend the enrolment phase will end on September 2007 and the study is expected to be closed on September 2009.

Results

Costs of baseline scenario will be ready by the end of 2007. the cost-effectiveness analyses will end in the net two years.

Conclusion

The PRECISE study is the first Italian study aiming at the evaluation of the FBSS burden on society and of the cost-effectiveness of SCS treatment. This study will provide useful information in order to support decision makers in the process of health care resources allocation and will set the basis for the development of further studies.

Acknowledgements

Medtronic Italy is contributing to this research.

Learning Objectives

Needs of cost-effectiveness analysis on SCS treatment for FBSS

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Tuesday, December 11
1720-1727
Marquesa III-IV (16)

18. Stimulation coverage of transverse tripole programming using the Lamitrode® Tripole™ 16 surgical lead: Preliminary evaluation of a prospective, multi-centered, post-market study.

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Vytas Rupinskas

Introduction

Spinal cord stimulation (SCS) is a popular treatment modality for chronic pain, especially Failed Back Surgery Syndrome. However, stimulation coverage of axial pain is often difficult to obtain and/or maintain. The Lamitrode® Tripole™ 16C leads (ANS; Plano, TX) are paddle leads are technologically advanced for hard-to-cover back pain.

Materials and Methods

Data is being collected from an ongoing clinical research study being conducted with patients implanted with the Eon® Neurostimulation System (ANS; Plano, TX). The physician used his medical judgment in determining the best lead configuration for each patient. After informed consent is obtained, the patients are evaluated prior to the system implant, and then return for evaluation at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years post implant. After the 3 month visit was completed, patients were asked to return to the clinic for a programming test visit. Pain scores, pain location, patient satisfaction, and quality of life measures were completed prior to the programming test. A series of 5 tests were performed, adding lateral and longitudinal guarding as the tests progressed. Stimulation coverage was documented after each test.

Results

Data presented consists of preliminary results from 5 patients enrolled at one clinical site who were implanted with the Lamitrode® Tripole 16C surgical lead and completed the programming test visit.

Conclusions

The in-line tripolar electrode configuration allows use of anodal guarding to confine the cathodic field to desired fibers, which allows a broad amplitude range between perception and discomfort thresholds. In addition, the availability of sixteen independently controlled electrodes offers extensive programming flexibility to cover complex pain patterns.

Acknowledgements

The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:

1. Understand the difficulties in stimulation coverage of low back pain.
2. Recognize the advantages of in line transverse tripolar programming.

Tuesday, December 11
1730-1737
Marquesa III-IV (16)

19. Percutaneous lead tripolar arrays in the management of chronic intractable back pain: preliminary findings from one clinic in a prospective post-market study.

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Vytas Rupinskas

Introduction

Spinal cord stimulation (SCS) is a popular treatment modality for chronic pain, especially for patients with Failed Back Surgery Syndrome and other types of back pain. However, stimulation coverage of axial pain is often difficult to obtain and/or maintain. One approach is the use of a transverse tripolar electrode configuration. The following data present findings from one clinic involved in a prospective post-market study.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Materials and Methods

Data is being collected from a currently active clinical research study being conducted with patients implanted with the Eon[®] Neurostimulation System (ANS; Plano, TX) and a percutaneous lead tripolar electrode array. This study is a prospective, multi-centered, 2-year post-initial programming study. After informed consent is obtained, the patients are evaluated prior to system implant. Patients then return for evaluation at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years post implant. The following parameters are evaluated during the study: patient reported pain relief, patient reported satisfaction level, patient reported area of paresthesia coverage of their painful area, device programming, patient quality of life, and patient disability.

Results

Data presented is preliminary results from patients enrolled at one clinical site who have completed evaluations through the 6 month visit.

Conclusion

Patients have experienced good pain outcomes and increased quality of life since treatment with SCS and percutaneous lead tripolar electrode configurations.

Acknowledgements

The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:

1. Understand the difficulties in stimulation coverage of low back pain.
2. Recognize the advantages of transverse tripolar programming.

Tuesday, December 11

1740-1747

Marquesa III-IV (16)

20. Spinal cord stimulation versus conventional medical management: Quality of life, resource use and costs from a multicentre randomised controlled trial of patients with failed back surgery syndrome: (PROCESS study).

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Introduction

Patients with failed back surgery syndrome (FBSS) continue to experience persistent or recurrent pain, disability and reduced quality of life despite anatomically successful lumbosacral spine surgery. The aim of this randomised controlled trial was to evaluate the clinical (and cost-) effectiveness of the addition of spinal cord stimulation (SCS) to conventional medical management (CMM) in patients with FBSS.

Materials and Methods

This was a randomised controlled trial with 52 patients in the SCS group and 48 patients in the CMM group. Corresponding healthcare resource use data relating to screening, the use of the implantable generator in SCS patients, associated hospital stay, and drug and non-drug pain-related treatment were collected. Resource use was costed at 2005-2006 prices using UK and Canadian national figures. Health-related quality of life was assessed using the EuroQol-5D (EQ-5D) questionnaire. Costs and outcomes were assessed for each patient over their first 6-months in the PROCESS trial.

Results

After a 6-month follow-up period, the total mean patient cost was €12,820 in the SCS group (1€=1.37 \$U.S.) and €3,155 in the CMM group (adjusted difference: €9,519, $p < 0.0001$). The improvement in EQ-5D over time was appreciably greater in the SCS group, with mean utility gains of 0.25 ($p < 0.001$) and 0.21 ($p < 0.001$) at 3 and 6 months, respectively, after adjusting for baseline EQ-5D scores and patients' characteristics.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Conclusion

The addition of SCS to CMM in treating predominant leg pain in FBSS patients with predominant neuropathic pain results in higher costs to health systems over a 6-month period. This is, in part, due to the upfront cost of the device. However, SCS generates significant improvements in patients' health-related quality of life over the same period. A full cost-effectiveness analysis needs to be completed to understand how costs and quality of life differences develop over the long-term.

Acknowledgements

Contributors include A Manca, K Kumar, RS Taylor, L Jacques, S Eldabe, M Meglio, J Molet, S Thomson, Jim O'Callaghan, E Eisenberg, G Milbouw, E Buchser, G Fortini, J Richardson, RJ Taylor, Goeree R, Sculpher MJ. This study was supported by Medtronic.

Learning Objectives:

1. Understand the study design and methods used to conduct this RCT for interventional pain therapy
2. Be able to characterize the health-related quality of life of FBSS patients with predominant leg pain before and after treatment with SCS.
3. Speak to the cost consequence of SCS vs. CMM for FBSS over the first 6-month treatment period.

Tuesday, December 11

1750-1757

Marquesa III-IV (16)

21. Spinal cord stimulation versus conventional medical management: Long-term results from a multicentre randomised controlled trial of patients with failed back surgery syndrome: (PROCESS study).

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Introduction

Patients with failed back surgery syndrome (FBSS) continue to experience persistent or recurrent pain, disability and reduced quality of life despite anatomically successful lumbosacral spine surgery. The aim of this randomised controlled trial was to evaluate the clinical effectiveness of the addition of spinal cord stimulation (SCS) to conventional medical management (CMM) in FBSS patients.

Materials and Methods

Design: Multicentre, randomised controlled trial of 100 patients with persistent neuropathic pain, predominantly in legs despite successful lumbosacral spine surgery. Interventions: SCS plus CMM versus CMM alone. Primary Outcome Measure: $\geq 50\%$ leg pain relief at 6 months (VAS). Secondary Outcomes: Functional capacity (Oswestry), health related quality of life (HRQoL, Short-Form 36), patient satisfaction and adverse effects. Results focus on the subset of patients randomized to SCS that continued with SCS therapy through 24 months.

Results

In the 6-month intention to treat analysis (ITT), patients randomized to SCS had 9 times the odds of achieving the primary endpoint (OR=9.23, 99% CI 1.99-42.84). Compared to CMM alone, SCS patients experienced improved functionality ($p < 0.001$), improved HRQoL in 7 of 8 domains ($0.02 > P > 0.001$) and greater satisfaction in pain relief provided by their treatment ($P < 0.001$). At the 6 months visit, 73% ($n=32$) of patients in the CMM group requested to switch to SCS (compared to 10% ($n=5$) in the SCS group). For the subset of patients randomized to SCS that continued SCS therapy ($n=42$), 40% achieved the primary outcome of $\geq 50\%$ leg pain relief and 69% achieved $\geq 30\%$ leg pain relief at 24 months post-implant. Over 24 months, 26% of 87 patients receiving an electrode experienced a device-related complication requiring additional surgery.

Conclusion

Compared to CMM alone, SCS improves pain relief, health-related quality of life and functionality in predominantly neuropathic FBSS patients. The ability of SCS to provide significant pain relief is maintained over 24 months.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Acknowledgements

Contributors include K Kumar, RS Taylor, L Jacques, S Eldabe, M Meglio, J Molet, S Thomson, Jim O'Callaghan, E Eisenberg, G Milbouw, E Buchser, G Fortini, J Richardson, RB North. This study was supported by Medtronic.

Learning Objectives:

1. Understand the study design and methods used to conduct this RCT for interventional pain therapy
2. Be able to characterize the demographics, treatment history and other relevant baseline characteristics of FBSS patients
3. Speak to the clinical effectiveness of SCS vs. CMM for FBSS.

Wednesday, December 12

0700-0707

Princesa Ballroom B-C (13)

1. Effect of spinal cord stimulation assessed by positron emission tomography in patients with refractory angina pectoris

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Introduction

We investigated the influence of SCS on myocardial blood flow by positron emission tomography (PET) in the long term.

Methods

In 23 patients quantitative myocardial blood flow was studied using ^{13}N -ammonia-PET both at rest and during adenosin stress test before and after SCS (12 ± 3 months). Neuromodulation was active in all patients over 22 ± 5 hours before PET scan were done
For viability testing ^{18}F -FDG-PET was performed. Both patient-related and segment-related (20-segment model) evaluations were performed.

Results

In the patient-related evaluation the mean blood flow during stress test increased from 160.6 ± 55.2 ml/(100 g*min) before SCS to 165.5 ± 55.4 ml/(100 g*min) after SCS (not significant [n.s.]). With a smaller rate-pressure product the mean blood flow at rest decreased (from 75.8 ± 17.4 to 71.6 ± 20.1 ml/(100 g*min), n.s.). The segmental evaluation showed a significant increase in blood flow during stress test in the vital segments demonstrating a baseline flow of < 180 ml/(100 g*min) ($n = 215$, increase in mean flow from 118.6 ± 35.8 to 132.0 ± 50.0 ml/(100 g*min), $p < 0.001$). In the 15 patients who demonstrated a reduction in mean coronary resistance (CR) over the course, the mean CR was initially higher than in the 8 patients who demonstrated an increase in CR (0.69 versus 0.47 (mmHg*100g*min)/ml).

Conclusion

SCS increases myocardial blood flow in vital segments which are under-perfused during stress test. The effect of SCS seems to be larger in patients with initially significantly increased minimum CR. In well-perfused segments myocardial blood flow is reduced during stress test.

Learning Objectives:

1. SCS increases myocardial blood flow in vital segments
2. SCS leads to a reduction in mean coronary resistance

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Wednesday, December 12
0710-0717
Princesa Ballroom B-C (13)

2. Spinal cord stimulation in refractory angina pectoris treatment

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Introduction

The role of spinal cord stimulation (SCS) in refractory angina pectoris treatment is increasing, but its anti-ischemic effect isn't clear. This study aimed at evaluating long-term anti-ischemic effect .

(1, 2, 3)

Materials and Methods

65 patients (40 males and 25 females, mean age 77 +/- 8 yrs), suffering from angina pectoris refractory to medical treatment and unsuitable for surgical or percutaneous revascularization procedures (Canadian Class III-IV), were treated with SCS from 1990 to 2003 (mean follow up: 39 +/- 24 months).

We used quadripolar electrode (tip at C6-T1 level), pulse generator (Itrel 2 and 3), Rate: 70 Hz, Pulse Width: 270 msec, Amplitude is set to evoke acceptable paresthesia in angina pain site.

We studied

- Questionnaire score referred to angina, dyspnoea and asthenia before SCS and 6 months after
- Hospital admission 90 days before SCS and 90 days after SCS
- Life quality by Canadian Class
- Holter ECG monitoring during 48 h (24 h SCS off and 24 h SCS on)
- Myocardial blood flow by PET (First Time: after 24 h SCS off Second Time: after 4 h SCS on)

Results

The questionnaire score, referred to angina, dyspnoea, and asthenia decreased 6 months after SCS compared with the one before SCS.

Hospital admission decreased

Life quality by Canadian Class improved

Holter ECG monitoring (24 h SCS off , 24 h SCS on) showed decrease in ischemic episodes, ischemia duration, total ischemic burden.

Myocardial blood flow with PET, increased . (4)

Conclusion

This study shows SCS has anti-ischemic properties, in refractory angina pectoris

- improving anginal symptoms, workload capacity and life quality

- decreasing hospital admission.

Therefore it has to be considered a safe and effective therapeutic option for refractory angina.

References

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3. Augustinsson LE, Mannheimer C, Eliasson T, (1996) Spinal Cord Stimulation in cardiac pain Abstracts 7th International Symposium The Pain Clinic
4. Mobilia G., Neri G, Zuin G, Zanco P, Pinato GP, Di Pede F, et al Assessment, by positron emission tomography, of myocardial perfusion in patients with spinal cord stimulation. Eur Heart J 1997

Learning Objectives:

1. Therapeutic option for refractory angina



ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Wednesday, December 12
0720-0727
Princesa Ballroom B-C (13)

3. Systematic Review of the Role of Neurostimulation in Alleviating Chest Pain in Refractory Angina

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Thomas Stauss, M.D., Kostandinos Tsoulfas M.D., William Civiletti-Kalich, PA-C

Introduction

Neurostimulation has been used to treat inoperable and/or medically refractory angina pectoris for years. Its mechanism of action remains polemical. The aim of this study is to determine the feasibility, effectiveness, and safety of neurostimulation implantation in alleviating chest pain in refractory angina.^{1,2}

Materials and Methods

A systematic review of the medical and surgical literature regarding role of neurostimulation in refractory angina. All studies were reviewed based on Cochrane Collaboration evidence review criteria and meta-analysis of neurostimulation in refractory angina. Case series, cost effectiveness analysis, randomized trials and retrospective studies were reviewed. 40 research and clinical reports were reviewed for treatment outcomes of neurostimulation in refractory angina.

Results

Long term follow-up of neurostimulation in refractory angina demonstrated an overall decrease in the median number of angina attacks, decrease in the median number of nitroglycerin doses per week and decrease days of hospitalization. The reported success rate varies from 65% to 80%.

Conclusion

Neurostimulation has shown a positive effective role with regard to continued pain relief, increase level of functioning and improve quality of life. Neurostimulation modality provides an alternative safe reversible therapy for refractory angina with less long-term side effects and cost reduction. It does not disguise the ischemic chest pain, which is an alarming sign for myocardial injury that can be life threatening. The use of multipolar leads reduces the incidence of revisions.^{3,4}

References

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Learning Objectives:

1. The role of neurostimulation in refractory angina.
2. The safety and efficacy of neurostimulation in refractory angina.
3. The cost effect of neurostimulation in refractory angina.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Wednesday, December 12
0730-0737
Princesa Ballroom B-C (13)

4. Spinal Cord Stimulation Reduces the Occurrence of Ventricular Fibrillation in the Ischemic Canine Heart

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Introduction

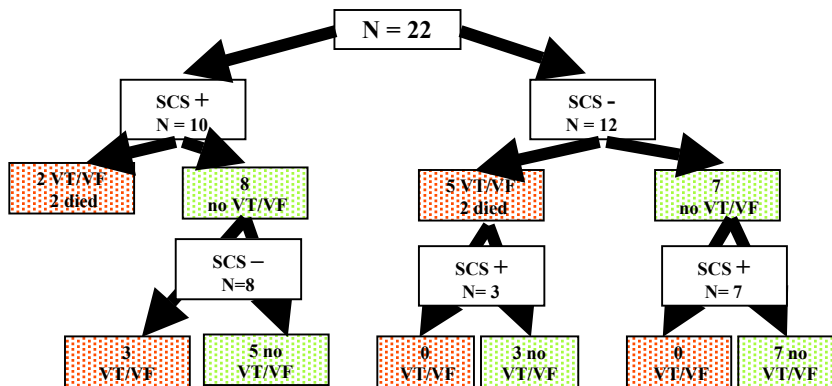
Spinal cord stimulator (SCS) for patients with refractory angina is considered as an effective analgesic adjunct therapy. In addition, SCS has antiischemic properties. However, with respect to its safety profile little is known about the effect of SCS on ventricular arrhythmia's. We therefore sought to study the impact of SCS on ventricular (tachycardia's and fibrillation [VT-VF]) arrhythmia's in an experimental setting.

Materials and Methods

In 22 canines a four-pole catheter electrode was introduced and advanced to T1, slightly left of the midline and connected to a SCS device, at least 1 week before the experiments. In the open chest model coronary artery occlusion (CAO) was made through tightening a ligature around the target coronary artery for 15 - 30 minutes. Stimulation was performed at 90% motor threshold, 250 ms, 50 Hz, starting 1 minute before CAO and continued, in random order, for 15-30 minutes. ECGs were ambulatory registered and digitally stored, making use of a commercially available Holter recording system.

Results

Out of the 22 canines, 10 were randomized to start with SCS. Twenty CAO were performed during active SCS and 20 CAO without active SCS (see Fig). In 2 out of 20 CAOs VT-VF was observed in the presence of SCS and in 8 out of 20 CAOs VT-VF was found when SCS was withheld.



Ventricular arrhythmias, following stressful events such as myocardial ischemia, induce inconsistent cardiac neuronal output, which on its turn leads to perturbations in cardiovascular brain center control. SCS is suggested to rebalance the neural hierarchy of cardiac control and so may stabilize (among others adrenergic peripheral and intra cardiac) neurons, involved in ventricular arrhythmias.

ORAL PRESENTATION ABSTRACTS AND SCHEDULE

Conclusion

SCS reduces the number VT-VF episodes significantly and therefore has a cardioprotective (i.e. safe) effect against severe life-threatening dysrhythmias, induced by critical coronary ischemia.

Acknowledgements

The investigators wish to thank ANS Inc, Plano, Tx and Medtronic Inc, Minneapolis, MN for their unrestricted grants.

Learning Objectives

1. SCS is considered as a safe therapy because of both, its antiischemic effect and the observed antiarrhythmic effect.
2. It is not yet clarified whether preemptive stimulation is required to employ the observed antiarrhythmic effect of SCS
3. The working mechanism of SCS may be related to stabilization of the disrupted (adrenergic) nervous system.