Washington State Department of Labor and Industries
Office of the Medical Director
Technology Assessment
Dynatron STS

I. Background

The Dynatron STS is a device manufactured by Dynatronics that addresses chronic pain conditions associated with the sympathetic nervous system. The Dynatron STS applies sympathetic therapy, a non-invasive treatment involving electrical stimulation.

Electrodes administer electrical currents to the lower legs, feet, arms, and hands. The electrodes are applied bilaterally to form four intersecting stimulation channels that follow the peripheral nerves across the spine. As a result, a patient's pain is resolved systematically rather than locally.

A patient may undergo twenty or more treatments before the establishment of an appropriate protocol. A clinician may prescribe a six-pound Dynatron STS Rx home unit for a patient who responds well to clinical Dynatron STS treatment. Daily, one-hour home treatments often extend indefinitely under the supervision of a clinician.

Contra-indications for use include thrombosis, pacemakers, defibrillators, cardiac conditions, neurological disorders, bacterial infections, pregnancy, and malignancy.[1]

II. Reason for OMD Review

A physician requested payment for Dynatron STS treatment in July 2001. In addition, the department is reviewing Dynatron STS to determine whether it is different from other interferential therapy devices, including the IF-400 device currently covered under the TENS contract. [2]

III. FDA Status and Indications for Use

Dynatron STS and Dynatron STS Rx received 510(k) classifications in May 2001 under the classification name Interferential Current Therapy Device.

The FDA has indicated Dynatron STS and Dynatron STS Rx for "providing symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain."[3]

IV. Literature Review

Two studies have been conducted on Dynatron STS:

a) Guido examined the effects of sympathetic therapy on chronic pain in peripheral neuropathy subjects.[4]

Study Design: The prospective case series assessed 20 patients who had been diagnosed with peripheral neuropathy. The subjects were treated with Dynatron STS for one hour each day for 28 days. The main outcome of pain was assessed with a visual analog scale.

Results: At baseline 11/15 patients reported moderate to severe pain. At final treatment, 5/15 subjects reported moderate to severe pain. 10 subjects reported complete relief from pain, and 19 patients reported significant pain relief. The mean global pain score decreased from 107.8 at baseline to 45.3 at 28 days.

Conclusion: The subjects showed improvement in pain indicators following sympathetic treatment therapy.

Data Limitations: The study did not include a control or comparison group. The small number of subjects was followed for a short period. The authors did not disclose the dropout rate. All data was based on self-report. Little consistency between subjects existed as pain sites and medical histories varied. Investigators did not attempt to influence or measure patient use of other treatments or medications. Although the response rate for questions was inconsistent, intention to treat was not used to analyze data.

b) An unpublished study by Sacks and Ernst showed the effect of sympathetic therapy on pain attenuation.[5]

Study Design: The retrospective case series assessed 197 patients suffering from chronic pain. Researchers grouped patient data according to the location of the subjects' pain to create 227 records. Subjects experienced pain in the lower extremity (116), upper and lower extremity (61), migraine (23), and upper extremity (27). Subjects received daily, 40-60 minute treatments for an unspecified number of days. The main outcome of pain and secondary outcomes of medication use, daily activities, and sleep improvement were assessed with a questionnaire.

Results: 64% of lower extremity, 62% of upper and lower extremity, 100% of migraine, and 93% of upper extremity subjects experienced mild to significant pain relief. 76% of lower extremity, 82% of upper and lower extremity, 100% of migraine, and 83% of upper extremity subjects indicated a decrease in their medication use.

Conclusion: Patients experience a reduction in pain and medication use following sympathetic treatment therapy.

Data Limitations: The study does not include baseline data or a control group. All data is based on self-report. Little consistency between subjects exists as pain sites and medical histories varied. Authors do not specify length of follow-up. Investigators did not influence use of other treatments and medications. Despite an inconsistent response rate to questions as well as substantial loss of follow-up, intention to treat was not practiced in data analysis.

Other studies evaluate the efficacy of interferential therapy (IFT):

c) Alves-Guerreiro compared the effect of three electrotherapeutic modalities on peripheral nerve conduction and mechanical pain threshold.[6]

Study Design: The randomized, double-blind trial with a control group included 40 healthy volunteers. The subjects either received no treatment (10), transcutaneous electrical nerve stimulation (TENS) (10), interferential therapy (IFT) (10), or action potential stimulation (APS) therapy (10). Researchers took measurements at 10-minute intervals for 45 minutes following treatment. Outcomes were neurophysiological effects based on compound action potentials (CAP) and hypoalgesic effects based on mechanical pain threshold (MPT).

Results: The investigators did not find significant differences between groups for negative or positive peak latency or peak-to-peak duration. IFT was significantly different at 25, 35, and 45 minutes following treatment compared to all other groups for peak-to-peak amplitude. Groups did not differ significantly for mechanical pain threshold measurements.

Conclusion: Neither TENS, IFT, nor APS produced a hypoalgesic effect. IFT produced a significant change in peak-to-peak amplitude compared to TENS and APS.

Data Limitations: The sample size within each group was small. A single treatment application in healthy individuals may not accurately represent clinical conditions.

d) Cramp studied the effects of transcutaneous electrical nerve stimulation (TENS) and interferential therapy (IFT) upon the RIII nociceptive and H-reflexes.[7]

Study Design: The randomized, double-blind trial with a control group examined the effect of TENS and IFT on ipsilateral RIII and H-reflexes. 70 healthy subjects received treatment with various frequencies (n=10 per group): control (0 Hz), TENS 1 (5 Hz), TENS 2 (100 Hz), TENS 3 (200 Hz), IFT 1 (5 Hz), IFT 2 (100 Hz), and IFT 3 (200 Hz). Investigators took measurements before, after, and up to 45 minutes following treatment. Pain was evaluated with a visual analog scale.

Results: All groups experienced significant changes over time for negative peak latency, peak-to-peak amplitude, and RIII area. Groups did not differ significantly for negative peak latency, peak-to-peak amplitude, H-reflex, RIII area, RIII maximum amplitude, or visual analog scale.

Conclusions: Neither TENS nor IFT affect the RIII or H-reflexes.

Data Limitations: The sample size within each group was small. A single treatment application in healthy individuals may not accurately represent clinical conditions.

e) Hurley examined the effect of interferential therapy electrode placement on acute low back pain. [8]

Study Design: The randomized, blinded, controlled trial followed 60 patients with acute low back pain. The subjects received interferential therapy (IFT) in the painful area and *The Back Book* (18), IFT around the spinal nerve and *The Back Book* (22), or only *The Back Book* (20). Subjects received 2-3 treatments per week until the therapist determined that patients had achieved maximum benefit. Investigators took measurements before treatment, at discharge, and at 3-month follow-up. Therapists were blinded to patients' questionnaire scores. The trial coordinator, who analyzed data, was blinded to patient treatment. Researcher used a self-administered pain rating index and a disability questionnaire to measure outcomes.

Results: All groups showed statistically significant improvement at 3-month follow-up for all outcomes. The IFT around the spinal nerve group showed statistically significant reduction in functional disability compared to other groups.

Conclusion: IFT electrode placement combined with *The Back Book* may affect low back pain functional disability.

Data Limitations: The number of treatment sessions that each subjects received varied. Each group consisted of a small subject number. Some baseline differences in raw measurements and personal characteristics existed between groups, but the differences were not statistically significant. Investigators did not influence or continue to measure medication use or pursuit of other treatments. All data is based on self-report.

f) van der Heijden examined the effect of interferential electrotherapy and pulsed ultrasound on soft tissue shoulder disorders.[9]

Study Design: The randomized, double-blind, placebo controlled two-by-two factorial trial followed 180 subjects up to 12 months. The patients presented with unresolved soft tissue shoulder pain and were randomized to no treatment (35), active IFT and active ultrasound (34), active IFT and sham ultrasound (39), sham IFT and active ultrasound (39), or sham IFT and sham ultrasound (33). All subjects also received exercise therapy. Outcomes include functional status, pain, and clinical status.

Results: 20% of controls, 23% of active IFT, 22% of sham IFT, 26% of active ultrasound, and 19% of sham ultrasound recipients observed improvement at six weeks. 40% of subjects in all groups observed improvement at three months. Groups did not differ significantly at twelve-month follow-up.

Conclusion: Neither electrotherapy nor ultrasound are effective as adjuvants to exercise therapy for shoulder disorders.

Data Limitations: Investigators did not attempt to influence or measure patient use of other treatments or medications.

g) Werners compared interferential therapy against motorized lumbar traction combined with massage in the management of low back pain.[10]

Study Design: The randomized trial with a control group followed 147 patients for 3 months after treatment. Patients reporting low back pain received either motorized lumbar traction with massage (73) or IFT (74) in 6 sessions over 2-3 weeks. Ten patients were lost due to attrition, and ten were lost during follow-up. Researchers measured outcomes with the Oswestry Disability Index (ODI) and a pain scale.

Results: Patients in both groups scored 30 on the ODI scale at baseline. At 3-month follow-up, the ODI scores decreased to 21 for IFT recipients and 22 for lumbar traction with massage subjects. IFT patient pain scores decreased from 50 at baseline to 42 at 3-month follow-up. Pain scores for patients receiving traction and massage decreased from 51 to 39.

Conclusion: At 3-month follow-up, IFT patients did not differ significantly from patients receiving lumbar traction with massage in disability or pain score improvement.

Data Limitations: The study does not include untreated or placebo subjects. Neither investigators nor subjects were blinded. Investigators did not influence or measure patient use of other treatments or medications. Only 60% of the patients completed the pain scale. Data analysis with intention to treat is uncertain.

V. Similar treatments

Dynatron resembles several other devices that deliver interferential therapy. Dynatron addresses pain by using eight electrodes applied to upper and lower extremities as opposed to other interferential units that apply four electrodes near pain sites.

The department allows one interferential unit under its current TENS contract with Performance Modalities, Inc. (PMI). The covered device, IF-400, is manufactured by American Imex of Irvine, CA.

Dynatron also provides electrical stimulation in a manner similar to transcutaneous electrical nerve stimulation (TENS). However, Dynatronics asserts that sympathetic therapy distinctly applies treatment systematically rather than locally. Unlike TENS, Dynatron uses the peripheral nervous system to normalize the sympathetic nervous system.[1]

VI. Costs

The Dynatron STS, which accommodates two people at a time, costs $5000. The Dynatron STS Rx has a manufacturer's suggested retail price of $4,000. The units are not available for rent.

VII. Professional Organizations

The American Academy of Physical Medicine and Rehabilitation, the Canadian Chiropractic Association, and the Canadian Physiotherapy Association do not endorse nor have policies regarding interferential current therapy for chronic pain.[11, 12, 13]

VIII. Other Insurers

The Centers for Medicare and Medicaid Services (CMS) Coverage Issues Manual does not address interferential therapy.

Bluecross of California does not cover either sympathetic therapy via Dynatron STS or interferential current therapy because they are "investigational/not medically necessary."[14]

Neither Aetna U.S. Healthcare nor the Regence Group covers interferential therapy because the therapy's effectiveness has not been established in peer-reviewed medical literature.[15, 16]

Humana covers interferential current stimulation for post-operative or post-traumatic pain 30 days after surgery or injury or for chronic pain of at least 3-month duration that is not responsive to other methods of pain management.[17]

IX. Conclusion

Insufficient evidence exists to determine Dynatron STS' effectiveness in the treatment of chronic pain.

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