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ELECTROCHEMICAL THERAPY OF PELVIC PAIN :

Effects of PEMF on Tissue Trauma

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ABSTRACT

- *Unusually effective and long-lasting relief of pelvic pain of gynecological origin has been obtained consistently by short exposures of affected areas to irradiation by a magnetic induction device producing short, sharp, magnetic-field pulses of a minimal 1amplitude to initiate the electrochemical phenomenon of Electroporation within a 25 cm. focal area. Treatments are short, fast-acting, economical and in many instances have obviated surgery. This report includes typical cases such as dysmenorrhoea, endometriosis, ruptured ovarian cyst, acute lower urinary tract infection, post-operative hematoma, and persistent dyspareunia in which pulsed magnetic field treatment has not, in most cases, been supplemented by analgesic medication. Of 17 female patients presenting with acute (n=13) and/or chronic (n=9) pelvic pain, 16 (89.8%) experienced marked, even dramatic relief and 2 (10.2%) less than complete pain relief after an average of three 15-minute treatments.*

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INTRODUCTION

This presentation is a report of clinical results in treating painful gynecological conditions using the model PAP-IMI-300 Magnetic Induction Device (MID), and touching on theoretical considerations that may relate to the efficacy and rapid effects of this particular device.

Medical literature of the past decade and earlier contains many reports of therapeutic effects of Pulsed Electromagnetic Fields (PEMF) in treating a variety of diseases ranging from cancer to infections. However, the great majority of these reports have related the effects to PEMF-induced hyperthermia. It is only recently that the non-thermal effects on cellular-level metabolism of high-energy pulses at low duty cycles has been recognized as a new therapeutic modality and, even in this context, although mentioned occasionally as an incidental effect, especially in the treatment of joint disease, there has been little focus on the amelioration of pain *per se*.

We have observed a significant increase in success rate in resolving pelvic pain of gynecological origin using a new type of PEMF generator that produces nanosecond pulses of much greater amplitude and higher frequency (UHF) than diathermic devices, and which has no significant hyperthermic effect on biological tissues (see comparison of pulsed electromagnetic field devices in Table B). The MID has been used in a number of therapeutic applications for approximately five years [1,2].

MATERIAL AND METHODS

The Magnetic Induction Device (MID) referred to in this report has the unique property of exciting sharp, high-amplitude pulses of UHF oscillations in an ionized plasma. The pulses are conducted from the generator chassis through a 180 cm. flexible cable to an impedance-matched coil about 20 cm. diameter.

The coil size, plasma volume and plasma composition, as well as the LC characteristics of the basic resonant circuit, may be varied to achieve specific pulse, frequency and energy parameters.

It is noted that the amplitude of the UHF oscillations within the pulses is orders of magnitude higher than that of other therapeutic PEMF systems, but at 3 pulses per second the effective energy level is less than 100 mW per cm² and has little or no diathermic effect.

Within these parameters, MID treatment is seen to have the novel bioelectrochemical effect of Electroporation (15) at cellular level, and offer a more rapid and efficacious

therapeutic modality in relieving pain, accelerating healing and, incidentally, preventing reproduction of infectious microorganisms, than other solid-state devices in this category.

Moreover, from the standpoint of safety, it is noted that in over 1,000 cases here and in Greece over a 5 year period, no side effects have been observed in subjects even with full-power treatments of up to an hour a day for prolonged periods, nor have side effects been observed in technicians operating the MID equipment over this period. No adverse effects relevant to this study have been observed; however, in other applications, a slight drop in blood pressure may be noted and rebound effects have been reported after repeated usage for prolonged periods when treatments were suddenly stopped.

The method of application is as follows: the subject (or object for *in vitro* experiments) is placed on a well-insulated, non-metallic platform at least 10 cm. above the ground plane and well away from any large metal masses that may cause malfunction. An average voltage on the order of 12 to 18 volts is induced in the proximity of the trauma site by the output coil. Actual skin contact is not required, so clothing need not be removed. Depending on the nature of the trauma, exposure time may be varied from 15 to 30 minutes and repeated in cases of extensive tissue damage or disease on subsequent days.

A single treatment may suffice to normalize localized infections and mild inflammatory conditions; however, chronic pain and systemic infections may require repeated treatment at different or overlapping loci. In serious cases of large or deep-seated tumors or trauma areas, two or three 15-20 minute treatments per week may be required over a month or so, with possibly infrequent maintenance treatments for some period.

CLINICAL FINDINGS (See Table A)

Of 17 female patients of average age 32.6 years presenting with 20 episodes of acute (n=13) and/or chronic (n=9) pelvic pain between August 1992 and August 1993, receiving an average of 3 short treatments on subsequent days. In five episodes, patients also complained of dysmenorrhoea arising from one or more of the following specific diagnoses:

16 Ruptured ovarian cysts 2 Uterine fibroids

2 Postop pelvic hematomas 5 Dyspareunia

2 Urinary tract infection 3 Endometriosis

Fifteen patients in 18 episodes of pain experienced marked (and in most cases dramatically fast) pain relief, and in 2 of the total 20 episodes (10%) only slight (non-significant) relief was reported; these 2 were considered to require further psychological or psychiatric treatment.

In 18 of the 20 episodes (90%) the pain subsided within one to three days, permitting an early return to normal life and regular physical activities, in some cases obviating the alternative of surgical intervention. This, incidentally, suggests a marked acceleration of the healing process of the underlying pathology.

With the exception of one, possibly two cases, there has been no recurrence of the condition for which the patient was treated. No patient reported any negative side effect or aggravation of their symptoms during or following treatment.

It is noted that 14 of the patients treated were diagnosed with a ruptured ovarian cyst that probably caused bleeding into the peritoneal cavity and resulted in acute pain. This condition usually demands hospitalization and sedation, and frequently requires surgical evacuation of the hemoperitoneum and cauterization. In such cases, it is not unusual for a patient to be immobilized during convalescence for a week or more.

We have found that by treating these patients with the MID as described above, they are able to return to work or normal activities in one or two days, require little or no analgesic medication, and experience far less anxiety or depression throughout the episode.

In these cases, and also in the two cases of painful postoperative pelvic hematoma, we suspect that the unusually rapid pain relief after MID treatment is, at least in part due to the effect of the MID in accelerating the rate of resorption of the blood and fluid in the pelvic cavity. This speculation is supported by ultrasounds done on a post-operative case before and after treatment that clearly demonstrate an unusually rapid disappearance of the hematoma.

Two patients presented with chronic pelvic pain due to urinary tract infections of several years duration. Each of these received four treatments that eliminated the pain, one without recurrence in a 1-year follow-up, and the other too recent to evaluate.

THEORETICAL CONSIDERATIONS

Localized analgesia without proprioception was demonstrated using skin-contact stimulation by 0.3 to 5.0 volt pulses delivering <0.5 mA of current at frequencies ranging from 45 to 400 Hz [3]. The theoretical explanation of this effect is based on the Melzak

and Wall "Gate Control" theory that the hyperstimulation of large-diameter somatic afferent fibers (A-beta) would block out proprioception from that area [4].

According to this theory, such nerve fibers are constantly discharging nerve impulses at some (normally low) periodic rate below the pain perception threshold; this tonic activity is responsible for a number of sustained homeostatic bodily conditions. This homeostatic firing rate increases sharply with pain stimuli, exceeding the pain perception threshold within a certain firing-frequency window up to a point of overload above that rate window where the CNS ability to recognize pain signals is "swamped."

In addition to other effects of MID irradiation, and in the light of experimental results [5] and our clinical experience, it may be postulated that the shock-excitation of proprioceptor cells by the steep-edged MID pulses at a low repetition rate can induce a long-lasting "swamping" effect of pain perception in the CNS without producing hyperthermia.

Pain attenuation is also a function of healing rate. It is known that damaged or diseased cells present an abnormally low transmembrane potential (TMP) on the order of 20% of the TMP of a healthy cell [6,7]. This signifies a greatly reduced metabolism and, in particular, impairment of the Na/K pump¹ activity and ATP production [8,9].

As early as 1941, Nobel Laureate Albert Szent-Gyorgyi [10] established that structured proteins behave like solid-state semiconductors or rectifiers. In recent years it has been determined that cell membranes, having a characteristic of non-linear impedance, rectify an alternating voltage (in this case caused by currents induced by the strong-time-varying magnetic pulses). This property causes potential changes in the inner and outer cell membrane surfaces such as to increase the TMP and effectively stimulate the activity of the Na/K pump¹ and normal cell metabolism.

In fact the TMP is proportional to the activity of this pump¹, and thus to rate of healing.

With respect to tissue regeneration an additional mechanism may be cited: at a trauma site (e.g. burns, wounds, necroses) damaged cells are normally replaced by either cells that differentiate to assume normal function (regeneration) or undifferentiated cells that form scar tissue. The development of replacement cells (dormant Schwann cells on the neurilemma of adjacent myelinated nerve fibers that are drawn toward the trauma site by the change in tissue potential that characterizes traumas) is dependent on their TMP; if adequate they will differentiate to regenerate the damaged tissue, but if not they will form undifferentiated and non-functional scar tissue [11]. In view of the extraordinary trauma-healing effects of MID irradiation [12] it appears that the TMP of undifferentiated Schwann cells is raised to the point of regeneration by this process.

With respect to the rapid cure of urinary tract infections, it has been demonstrated *in vitro* and *in vivo* that MID irradiation is capable of preventing reproduction of or destroying single-celled microorganisms at a remarkably rapid rate [13,14]. As these organisms reproduce by division only when their TMP falls to the level where cell division is

triggered, it seems reasonable to suppose that when a bacterium or virus is prevented from dividing by the induction of a high TMP, it will soon expire from starvation and/or age.

CONCLUSIONS

Eighteen of 20 episodes of gynecological pelvic pain (89.5 %) were successfully treated in a remarkably short time by brief (15 to 30 minute) exposures to a Magnetic Induction Device generating extremely short electromagnetic pulses at very high peak power and very low average power in a non-diathermic mode. There was evidence of accelerating pain relief as a possible neurological effect, accelerated healing at a cellular level and clearance of urinary tract infection.

However, rapid pain relief was a primary objective because with the use of the MID we have accomplished:

- Reduction of treatment time and costs.
- Avoidance of hospitalization and, in some cases, surgical intervention.
- Rapid return of patients to work and normal life styles.

Although we have not been able to confirm reports of fibroid size reduction using electromagnetic therapy with this series of patients, the efficacy of this method of pain relief on our limited cohort, together with its absence of adverse side effects and risk of hyperthermic tissue damage appear to warrant further clinical investigation.

| PATIENT | AGE | START | R | AP | CP | CR | CL | UT | PH | UF | DP | DM | EN | IMPROV |
|-------------------|-----|-------|----|----|----|----|----|----|----|----|----|----|----|--------|
| 1 MB | 46 | 8/92 | 3 | X | | X | | | | | | X | | GOOD |
| 2 LB | 39 | 9/92 | 2 | | X | | | | | | | | | GOOD |
| 3 DB | 55 | 8/92 | 2 | | X | | | | | | | | | GOOD |
| 4 KD | 37 | 6/93 | 2 | X | | | X | | X | | X | X | X | GOOD |
| 4 KD | 37 | 7/93 | 3 | X | | | X | | | | | | | GOOD |
| 5 RE | 21 | 10/92 | 4 | X | X | X | | | | | | X | X | GOOD |
| 6 JF | 33 | 5/93 | 3 | | X | X | X | | | | | | | GOOD |
| 7 MM | 27 | 8/92 | 4 | | X | | | X | | | | | | GOOD |
| 7 MM | 28 | 4/93 | 2 | X | | | X | | | | | | | GOOD |
| 8 DM ¹ | 38 | 11/92 | 11 | | X | | | | | X | X | X | | GOOD |

| | | | | | | | | | | | | | | |
|--------------------|------|---------|----|----|----|----|----|----|----|----|----|----|----|---------|
| 9 JN | 22 | 12/92 | 4 | X | | X | | | | | X | | | GOOD |
| 9 JN ² | 22 | 6/93 | 1 | X | | | X | | | | X | | | FAIR |
| 10 AN | 26 | 8/92 | 1 | X | | X | | | | | | X | X | GOOD |
| 11 MR | 43 | 7/93 | 2 | | X | | | | | | | | | GOOD |
| 12 ER | 31 | 5/93 | 2 | X | | | X | | X | | | | | GOOD |
| 13 DS ³ | 37 | 8/92 | 8 | X | X | | X | | | X | | | | GOOD |
| 14 AS | 26 | 9/92 | 2 | X | | X | | | | | | | | GOOD |
| 15 MT ⁴ | 22 | 4/93 | 2 | X | | X | | | | | | | | FAIR |
| 16 JV | 26 | 9/92 | 2 | X | | | X | | | | | | | GOOD |
| 17 SB | 26 | 8/93 | 2 | | X | | | | | | | | | GOOD |
| AVERAGES | 32.6 | 4.4 DAY | 3 | | | | | | | | | | | 89% |
| TOTALS 20 | | 12 MOs | 62 | 13 | 9 | 6 | 8 | 2 | 2 | 2 | 5 | 5 | 3 | 18 GOOD |
| INCIDENTS | | | ? | AP | CP | CR | CL | UT | PH | UF | DP | DM | EN | |

TABLE A

= Number

AP = Acute Pelvic Pain

PH = Postoperative Pelvic Hematoma

CP = Chronic Pelvic Pain

UF = Uterine Fibroid(s) 17 Patients with 20 episodes of pelvic

CR = Ruptured Right Ovarian Cyst

DP = Dyspareunia pain treated solely with the PAP-300

CL = Ruptured Left Ovarian Cyst

DM = Dysmenorrhoea Magnetic Induction Device and, in most

UT = Urinary Tract Infection

EN = Endometriosis cases, without any supplementary analgesic medication.

NOTES:

1. DM receive 11 treatments for persistent uterine bleeding from submucous fibroid with little effect; three or four weeks after last treatment,

patient required emergency myomectomy.

2. JN appeared psychologically addicted to her analgesic medication and seemed reluctant to report complete pain relief out of concern that she

would not be able to get her prescriptions renewed.

3. DS ultrasound indicated a small reduction in fibroid after 8 treatments, but patient lost to follow-up. 4. MT suffered from anxiety and reported only mild relief; patient recommended for psychological counselling and reassurance.