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Electrochemical Therapy of Pelvic Pain: Effects of Pulsed Electromagnetic Fields (PEMF) on Tissue Trauma

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ABSTRACT

Unusually effective and long-lasting relief of pelvic pain of gynaecological origin has been obtained consistently by short exposures of affected areas to the application of a magnetic induction device producing short, sharp, magnetic-field pulses of a minimal amplitude to initiate the electrochemical phenomenon of electroporation within a 25 cm^2 focal area. Treatments are short, fasting-acting, economical and in many instances have obviated surgery. This report describes typical cases such as dysmenorrhoea, endometriosis, ruptured ovarian cyst, acute lower urinary tract infection, post-operative haematoma, 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 a total of 20 episodes of pelvic pain, of which 11 episodes were acute, seven chronic and two acute as well as chronic, 16 patients representing 18 episodes (90%) experienced marked, even dramatic relief, while two patients representing two episodes reported less than complete pain relief.

Key words: electrochemical therapy (ECT), pain relief, pulsed electromagnetic fields, trauma, palliation, electroporation.

INTRODUCTION

This presentation is a report of clinical results in treating painful gynaecological conditions using a non-invasive probe to deliver pulsed electromagnetic energy to the trauma site. It will also discuss certain theoretical considerations that may relate to the efficacy and rapid effects of this principle.

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 non-thermal effect on the cellular-level metabolism of high-energy pulses at low duty cycles has been recognised 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 gynaecological origin using a new type of PEMF generator that produces nanosecond electromagnetic 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 II). The magnetic induction device (MID) has been used experimentally in a number of other therapeutic applications with favourable results.

MATERIAL AND METHODS

Electromagnetic energy delivered by the MID produces sharp, high-amplitude pulses of UHF oscillations in an ionised 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 in orders of magnitude higher than those of other therapeutic PEMF systems, but at three pulses per second the effective energy level is less than 100 mW per cm^2 and has little or no diathermic effect.

Within these parameters, MID treatment is seen to have the novel bioelectrochemical effect of electroporation (11) at cellular level and offers 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 1000 cases in the US and Greece over a five-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,

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Table I. *Seventeen patients with 20 episodes of pelvic pain treated solely with the PAP-300 Magnetic Induction Device and, in most cases, without any supplementary analgesic medication*

AP = Acute pelvic pain, CP = Chronic pelvic pain, CR = Ruptured right ovarian cyst, CL = Ruptured left ovarian cyst, UT = Urinary tract infection, PH = Postoperative pelvic haematoma, UF = Uterine fibroid(s), DP = Dyspareunia, DM = Dysmenorrhoea, EN = Endometriosis.

Patient	Age	Start	R	AP	CP	CR	CL	UT	PH	UF	DP	DM	EN	IMPROV
1	46	8/92	3	X		X						X		Good
2	39	9/92	2		X									Good
3	55	8/92	2		X									Good
4	37	6/93	2	X			X		X		X	X	X	Good
4	37	7/93	3	X			X							Good
5	21	10/92	4	X	X	X						X	X	Good
6	33	5/93	3		X	X	X							Good
7	27	8/92	4		X			X						Good
7	28	4/93	2	X			X							Good
8	38	11/92	11		X					X	X	X		Good
9	22	12/92	4	X		X					X			Good
9	22	6/93	1	X			X				X			Fair
10	26	8/92	1	X		X						X	X	Good
11	43	7/93	2		X									Good
12	31	5/93	2	X			X		X					Good
13	37	8/92	8	X	X		X			X				Good
14	26	9/92	2	X		X								Good
15	22	4/93	2	X		X								Fair
16	26	9/92	2	X			X							Good
17	26	8/93	2		X									Good
Averages	32.6	4.4	Day 3											89%
Totals 20 Incidents		12 Mos	62 R	13 AP	9 CP	6 CR	8 CL	2 UT	2 PH	2 UF	5 DP	5 DM	3 EN	18 Good

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 in the order of 12 to 18 volts (V) 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 or alternate days.

A single treatment may suffice to influence on 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 tumours 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 (Table I)

Seventeen 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 received an average of three short treatments on subsequent or alternate days. In five episodes, patients also complained of dysmenorrhoea. Other diagnoses were: 16 ruptured ovarian cysts, two postoperative pelvic haematomas, two urinary tract infections, two uterine fibroids, five dyspareunia and three endometriosis.

Sixteen patients in 18 episodes of pain experienced marked (and in most cases dramatically fast) pain relief, and in two of the total 20 episodes (10%) only slight (non-significant) relief was reported; these two 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 12 of the patients treated were diagnosed with a ruptured ovarian cyst that probably

Table II. *Comparison of therapeutic PEMF devices*

Note: The PAP-IMI300 Magnetic Induction Device used in this investigation is the only known therapeutic PEMF device that operates close to the minimum electroporation gradient of 1 KV/cm. Electroporation (11) is a universal, non-thermal, bioelectrochemical phenomenon relating to the rate of two-way transmigration of chemical ions through the cell membrane, defining the cell's metabolic rate and hence energy level.

Device	MFR's specs					
*FDA approved **FOC	Pulses per reg. second	Frequency within pulses	Max therm energy joules/s	Peak E/M power watts	Ratio pulse interval to width	Duty cycle %
PAP-IMI300 magnetic induction pulsed E/M	2 to 30	1–250 MHz complex plasma technology	40 to 60	>1 M	100.000	0.001%
Diapulse *USA 21K pulsed E/M	80 to 600	27 MHz** vac tube technology	38	975	26–192	3.9–52%
Magnatherm *US 16K diathermy	70 to 7000	27 MHz** vac tube technology	665	1.000	3.33–1.33	30–75%
Zimmer *Eur. 16K diathermy		27 MHz** solid state	150	250	1.66	60%
Curapuls 403 *Eur pulsed E/M	26 to 400	27 MHz** solid state	32	200	100–6.25	1–16%

caused bleeding into the peritoneal cavity and resulted in acute pain. This condition usually demands hospitalisation and sedation, and frequently requires surgical evacuation of the haemoperitoneum and cauterization. In such cases, it is not unusual for a patient to be bedridden during convalescence for four to seven days or even longer.

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

Pain is often linked to specific physiological conditions such as impeded circulation, the pressure of vascular leakage and oedema, which often cascades to increase its intensity and prolongation. In these cases, and also in the two cases of painful post-operative pelvic haematoma, we suspect that the unusually rapid pain relief after MID treatment was, 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, which clearly demonstrated unusually rapid disappearance of the haematoma.

Two patients presented with chronic pelvic pain due to urinary tract infection of several years' duration. One patient received two treatments and the other patient received four treatments, which eliminated the pain, one without recurrence in a one-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 V to 0.5 V pulses delivering <0.5 mA of current at frequencies ranging from 45 Hz to 400 Hz (7). The theoretical explanation of this effect is based on the Melzak and Wall "gate control" theory that the hyper-stimulation of large-diameter somatic afferent fibres (A-beta) would block out pain transmission along the thinly myelinated A-delta and unmyelinated C-nerve fibres.

According to this theory, such nerve fibres 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 homoeostatic bodily conditions. This homoeostatic 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 ability of the central nervous system to recognize pain signals is "swamped".

In addition to other effects of MID irradiation, and in the light of experimental results (4) 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 central nervous system 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) in the order of 20% of the TMP of a healthy cell (3, 5). This signifies a greatly reduced metabolism and, in particular, impairment of the Na/K pump activity and adenosine triphosphate (ATP) production (1, 6).

As early as 1941, Nobel Laureate Albert Szent-Györgyi (8, 9, 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 pump and normal cell metabolism. In fact the TMP is proportional to the activity of this pump, 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 either by cells that differentiate to assume normal function (regeneration) or by undifferentiated cells that form scar tissue.

The development of replacement cells (dormant Schwann cells on the neurilemma of adjacent myelinated nerve fibres that are drawn towards the trauma site by the change in tissue potential that characterized 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 (2). In view of the extraordinary trauma-healing effects of MID exposure it appears that the TMP of undifferentiated Schwann cells is raised to the point of regeneration by this process.

With respect to the 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 (12). 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 gynaecological 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 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:

1. Reduction of treatment time and costs.
2. Avoidance of hospitalization and, in some cases, surgical intervention.
3. 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 in our limited cohort, together with the absence of adverse side effects and risk of hyperthermic tissue damage, appear to warrant further clinical investigation.

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