Advances In Therapy® | *Volume 19 No. 1 January/February 2002*

Advances In Natural Therapy™

Impulse Magnetic-Field Therapy for Erectile Dysfunction: A Double-Blind, Placebo-Controlled Study

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ABSTRACT

This double-blind, placebo-controlled study assessed the efficacy of 3 weeks of impulse magnetic-field therapy for erectile dysfunction (ED). Twenty volunteers who suffered from ED or orgasmic disturbances were randomly assigned to either active treatment or placebo (n = 10 each). Efficacy was assessed in terms of intensity and duration of erection, general well-being, sexual activity, and warm sensation in the genital area. In the active-treatment group, all efficacy endpoints were significantly improved at study end ($P \leq .01$), with 80% reporting increases in intensity and duration of erection, frequency of genital warmth, and general well-being. The remaining 20%, who experienced minor improvements, were found to have an influenza-like infection after the study that may have influenced their results. Only 30% of the placebo group noted some improvement in their sexual activity; 70% had no change. No side effects were reported.

Keywords: erectile dysfunction; magnetic waves; alternative therapy; impulse magnetic-field therapy

INTRODUCTION

Male sexual dysfunction can take several forms. One of them is erectile dysfunction (ED), the consistent inability to maintain an erect penis with sufficient rigidity to allow sexual intercourse. After premature ejaculation,

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ED is the most common sexual problem in men, affecting up to 30 million in the United States.[1] Epidemiologic studies have demonstrated that 39% of French men 18 to 70 years of age have some degree of ED, and 11% have complete ED.[2] In the United Kingdom, approximately 17% to 19% of men are thought to suffer from ED.[3,4] In a society that widely promotes sexuality, ED exerts a powerful negative effect on feelings of self-worth and self-confidence and may impair the quality of life of men and their partners. The ensuing damage to personal relationships can influence all aspects of life.[1]

RISK FACTORS

Various studies have uncovered significant associations among depression, cardiovascular disease, and ED. Age, heart disease, hypertension, sedentary behavior, related medication, cigarette smoking, and abnormal lipid levels have been implicated in all three medical conditions, which share many of the same risk factors and etiologic relationships. Patients with sexual dysfunction appear likely to have comorbid cardiovascular disease and depression, as well as the potential increased risk for cardiac mortality.[5]

Treatment of cardiovascular diseases or depression with antihypertensives and psychotherapeutic agents (especially selective serotonin reuptake inhibitors) accounts for approximately 25% of ED cases. This leads to noncompliance, as ED is usually reversible when use of the offending agent is discontinued or a suitable alternative is substituted.[6,7]

Midlife changes may occur too late to reverse the effects of smoking, obesity, and alcohol consumption on ED. In contrast, physical activity may reduce risk, even if initiated in middle age. Early adoption of healthful lifestyles, therefore, may be the best approach to reducing the burden of ED on the health and well-being of older men.[8]

PATHOPHYSIOLOGY

Normal penile erection is a hemodynamic process that depends on smooth-muscle relaxation mediated by parasympathetic neurotransmission, nitric oxide, and possibly other regulatory factors and electrophysiologic events.[9] Desire (sexual interest in the partner), sex drive (the mental state leading to fantasy and sexual behavior such as masturbation), the ability to reach orgasm, and ejaculatory capacity may all remain intact in the presence of ED.[10]

ED may have arterial, venous, neurogenic, or psychogenic causes and should be clearly distinguished from problems with libido, ejaculation, and orgasm. A loss of libido may be the direct consequence of androgen deficiency, whether based on hypothalamic, pituitary, or testicular disease. Loss of emission (lack of seminal fluid during ejaculation) may result from retrograde ejaculation or from androgen deficiency. Premature ejaculation is generally an anxiety-related disorder, whereas loss of orgasm is usually of psychological origin.[11]

Two types of ED can be distinguished: primary (congenital) and secondary (spontaneous/situational). Secondary ED can be temporary or long term. Whereas temporary ED as a rule is of psychogenic origin, longer-term ED has mostly organic origins. Risk factors for ED are diabetes mellitus, hyperlipidemia, hypertonia, and smoking.[12]

ED is a major public health problem. Although recent work has focused on its medical and physical etiology, the importance of psychological factors should not be dismissed. Several cross-sectional studies have reported links between ED and depression, anger, and dominance. Whether these factors are prospectively associated with the risk of ED has yet to be established. Results from the Massachusetts Male Aging Study[13] (1987–1997) suggest that new cases of ED are likely to occur among men who exhibit a submissive personality.

MANAGEMENT OF ED

ED is a delicate problem that patients are often embarrassed or reluctant to discuss with their primary-care physicians. Unfortunately, many physicians also fail to promote open discussion of sexual dysfunction. If patients do ask for help, some conventional remedies such as revascularization or implantation of alloplastic erectile aids (penile prostheses) require major surgery and are appropriate only for a selected group of men with severe ED. Moreover, their long-term effect is relatively poor.[14] Recent UK management guidelines for ED listed several forms of treatment: psychosexual intervention, oral sildenafil, intracavernosal prostaglandin (alprostadil) injections, transurethral alprostadil, vacuum devices, and penile prostheses.[15] Oral medication is currently first-line therapy, and the arrival on the market of sildenafil has revolutionized the treatment of ED. Many men, however, are not suitable candidates for sildenafil,[16] the number of side effects is high, and many physicians lack sufficient understanding to reasonably prescribe the drug.[17]

Intracavernosal injection of prostaglandins such as PGE_1 elicits an erection in men with ED. An extensive study[17] has identified arterial lesions (atheroma) as a cause of ED, which prompted the classification of "vasculogenic" ED. A major drawback of intracavernosal injection of PGE_1, however, is significant local pain in as many as 40% of patients, compared with the minimal systemic side effects following intrapenile injection. Nevertheless, intracavernosal PGE_1 is recognized as a therapeutic advance, because papaverine, another widely used agent for ED, may cause unwanted prolonged erections in up to 9.5% of patients (the rate with PGE_1 is lower).[18]

IMPULSE MAGNETIC-FIELD THERAPY

Magnetic pulse fields induce an alternating current within the body's electrolytes. This affects the cells' water content, mitochondrial function, physical properties of the membranes, nutrient, oxygen and amino-acid uptake, energy production, ion membrane permeability, and macrophage migration. Magnetic fields in adequate forms and doses can increase oxygen uptake by the cell, enhance blood circulation, and reverse functional impairment.

Recent studies have shown that magnetic pulse fields are effective in the treatment of psychogenic disorders.[19-24] A magnetic pulse field located in an area of pain induces an increase in blood flow, which, combined with muscular relaxation, exerts a positive influence on the entire system.

Recent studies in dogs[25] and healthy human volunteers[26] demonstrated that sacral magnetic stimulation of both the full and the empty rectum significantly increased rectal and vesical pressure and decreased anal pressure. Intermittent magnetic stim-

ulation achieved evacuation of the full rectum. Magnetic stimulation was also used for the treatment of patients with constipation due to rectal inertia.[27]

In the canine study,[28] magnetic stimulation of the cavernous nerve raised intracorporeal pressure and produced full penile erection after a mean latency of 7.8 ± 2.5 seconds. On discontinuation of stimulation, erection and intracorporeal pressure returned to baseline status after a mean of 14.2 ± 3.2 seconds. The response returned after an off-time of 50 seconds and was reproducible infinitely, provided that the off-time was observed. Results in the canine model prompted a study in 32 patients with neurogenic ED and 20 healthy volunteers.[29] A magnetic coil was placed over the dorsal aspect of the penis in the vicinity of the symphysis pubis. For 10 minutes, magnetic stimulation at 40% intensity and 20-Hz frequency, 50 seconds on and 50 seconds off, led to gradual increases in length and diameter until full erection was achieved; the penis became firm, rigid, and pulsatile. Intracorporeal pressure also increased significantly ($P<.0001$) at full erection. The study demonstrated that magnetic stimulation is a simple, noninvasive method that produces no adverse effects and might be suitable for patients with ED.

The aim of the present study was to verify the hypothesis that, as a result of their hemodynamic vasoactive properties, low-frequency pulsed magnetic waves exert a positive effect on orgasmic disturbances and on erectile potential.

PATIENTS AND METHODS

This study used a specifically designed impulse magnetic-field device that generates ELF waves (extreme low-frequency magnetic waves) at a field strength of 5 µTs. The impulse frequency was 18 Hz, close to the pulse frequency of the earth. The matchbox-sized device (Explorer Bio-Potenzor/Meteco, Berlin, Germany) had to be carried in the genital area (maximum distance, 50 cm).

Impulse magnetic-field therapy was administered for 3 weeks to 20 men suffering from ED and orgasmic dysfunction, who were between 30 and 60 years of age. Patients from whom good compliance could be expected were randomly assigned to either an active-treatment or placebo group (n = 10 each).

Men suffering from impotence of mainly somatic origin were excluded. Other exclusion criteria were acute infectious or severe organic diseases (arteriosclerosis, diabetes mellitus, ulcer, major surgery or myocardial infarction within the preceding 12 months), as well as use of the following medications within the preceding 6 months: thrombocyte-aggregation inhibitors, dipyridamole, sulfinpyrazone, antiphlogistics, corticosteroids, or immunosuppressives.

Study participants were volunteers; however, the delicate nature of the investigation may have introduced some bias, as only men willing to admit their sexual problem to the physician (and thereby "reveal" it publicly) volunteered.

The active-treatment group received the device; the placebo group received a nonoperative device of similar appearance. All patients had to wear the device no more than 50 cm from the genitals as regularly as possible for 3 weeks.

A medical examination was conducted before and after the treatment, and clinical data were collected at those times. Efficacy endpoints were intensity of erection, general well-being, and sexual activity. Symptoms were assessed on an 11-point scale (0 = no/minimal expression to 10 = maximal expression). At the end of treatment, patients were asked to evaluate the mean duration of their erection (in minutes)

during sexual contacts and the frequency of warmth in the genital area (during the 3 study weeks).

Safety was assessed in terms of incidence of adverse events.

Statistical Analysis

The following statistical methods were used: χ^2 test for random sample survey of nominal rating values; Mann-Whitney *U* test for random sample survey, Wilcoxon test for specific sample survey (the latter two only for the scales with the least similar intervals); *t* test for two random and two specific sample surveys; and analysis of variance of interval scale values with normal distribution. Results were expressed as means ± standard deviation.

RESULTS

Twenty volunteers were enrolled and completed the study. Data from the entire enrollment were analyzed.

The table shows changes in efficacy endpoints before and after treatment.

Efficacy Endpoints Before and After Treatment

Symptom*	Before Treatment		After Treatment		Change, %		Significance	
	Placebo	Treatment	Placebo	Treatment	Placebo	Treatment	*P*<†	*P*<‡
Intensity of erection	2.1	2.0	3.2	7.1	52	255	.001	.001
Well-being	2.0	2.8	3.6	7.9	80	182	.001	.001
Sexual activity	1.8	2.0	3.2	7.8	78	290	.001	.001
Duration of erection, min	–	–	6.3	30.1	–	–	.01	–
Frequency of warm sensation/week	–	–	1.5	5.7	–	–	.01	–

*Scored on an 11-point scale.
†Placebo vs active treatment at end of treatment (*U* test).
‡Before vs after treatment in active-treatment group (Wilcoxon test).

Initial values did not differ significantly between the active-treatment and placebo groups. On average, however, the active-treatment group wore the device for 18.6 hours daily, compared with approximately 22 hours daily for the placebo group. Values for all assessed criteria were significantly higher at the end of treatment ($P<.001$) in men assigned to the active device, 80% (n = 8) of whom reported an increase in the intensity and duration of erection and warm sensation. The remaining 20% of the active-treatment group (n = 2) reported only minor improvements; this result may have

been due to the influenza-like infection they experienced during the study. In contrast, only 30% of placebo patients (n = 3) noted an improvement in sexual activity; 70% (n = 7) saw no change in their status.

No treatment-related side effects or complications were reported.

DISCUSSION

The present findings confirm previous results on the efficacy of ELF waves in humans, demonstrating an essentially positive effect on symptoms that were difficult to treat.[30,31] Moreover, the increase in oxygen supply, secondary to increases in circulation, enhanced libido; this, in turn, led to improvements in general well-being. In this study ELF waves proved beneficial to men suffering from ED of different origins.

The device produced no side effects, again confirming the results of other studies.[31,32]

In industrialized nations, the prevalence of ED is growing. Oral agents like sildenafil, vacuum devices, and intracavernosal injections represent state-of-the-art therapy. The associated costs, however, are high, as patients often switch treatments owing to a lack of success. Treatment approaches should therefore focus on achievement of long-term satisfaction.[33]

The lack of adverse effects from the device, as well as the improvements experienced by a majority of patients, speaks to its viability as an economic and therapeutic option in ED.

Although the sample in this controlled study was small, the results were clear and significant. This device deserves further investigation with more participants, a longer time frame, additional endpoints, and more detailed diagnosis at the beginning of therapy. It would also be desirable to determine the effect of ELF waves in women, who are more frequently affected by sexual dysfunction than are men.[34]

REFERENCES

1. Korenman SG. New insights into erectile dysfunction: a practical approach. *Am J Med.* 1998; 105:135-144.
2. Virag R, Beck-Archily L. Nosology, epidemiology, clinical quantification of erectile dysfunction. *Rev Med Int.* 1997;1:10-13.
3. Goldmeier D, Keane FE, Carter P, Hessman A, Harris JRW, Renton A. Prevalence of sexual dysfunction in heterosexual patients attending a central London genitourinary medicine clinic. *Int J STD AIDS.* 1997;8:303-306.
4. Read S, King M, Watson J. Sexual dysfunction in primary care. Prevalence, characteristics and detection by the general practitioner. *J Public Health Med.* 1997;19:387-391.
5. Goldstein I. The mutually reinforcing triad of depressive symptoms, cardiovascular disease, and erectile dysfunction. *Am J Cardiol.* 2000;86:41-45.
6. Keene LC, Davies PH. Drug-related erectile dysfunction. *Adverse Drug React Toxicol Rev.* 1999; 18:5-24.
7. Waldinger MD, Olivier B. Selective serotonin reuptake inhibitor-induced sexual dysfunction: clinical and research considerations. *Int Clin Psychopharmacol.* 1998;13:27-33.

8. Derby CA, Mohr BA, Goldstein I, Feldman HA, Johannes CB, McKinlay JB. Modifiable risk factors and erectile dysfunction: can lifestyle changes modify risk? *Urology.* 2000;56:302-306.
9. Melman A, Gingell JC. The epidemiology and pathophysiology of erectile dysfunction. *J Urol.* 1999;161:5-11.
10. Levy A, Crowley T, Gingell C. Non-surgical management of erectile dysfunction. *Clin Endocrinol.* 2000;52:263-270.
11. McPhee SJ, Lingappa VR, Ganong WF, Lange JD. *Pathophysiology of Disease: An Introduction to Clinical Medicine.* 3rd ed. Los Altos, Calif: Lange Medical Books; 2000.
12. Psychorembel. In: *Klinisches Wörterbuch.* 258th ed. Hilderbrandt H, ed. Berlin: Walter de Gruyter; 1998.
13. Araujo AB, Johannes CB, Feldman HA, Derby CA, McKinlay JB. Relation between psychosocial risk factors and incident erectile dysfunction: prospective results from the Massachusetts Male Aging Study. *Am J Epidemiol.* 2000;152:533-541.
14. Manning M, Spahn M, Jünemann K-P. Gefäßflchirurgie, Implantationschirurgie und Vakuumerektionshilfe. *Urologie A.* 1998;37:509-515.
15. Khan MA, Thompson CS, Sullivan ME, Jeremy JY, Mikhailidis DP, Morgan RJ. The role of prostaglandins in the aetiology and treatment of erectile dysfunction. *Prostaglandins Leukot Essent Fatty Acids.* 1999;60:169-174.
16. Rutherford D, Duffy FJR. Current treatment of impotence: Viagra and other options. *Br J Nurs.* 1999;8:235-241.
17. Weig W. Die Rolle von Psychiatrie und Psychotherapie in der Sexualmedizin nach der Markteinführung von Viagra®. *Nervenarzt.* 2000;71:218-221.
18. Jeunemann K, Alken P. Pharmacology of erectile dysfunction: a review. *Int J Impot Res.* 1989; 1:71-93.
19. Akimov G, Ponizowski V. Effects of alternating field on healing of ulcers of the lower extremities. *Vestn Chir*. 1977;119:84-85.
20. Basset C, Pilla AA, Mitchell SN, Pawluk RJ. Nonoperative treatment of pseudoarthroses and nonunions by pulsing electromagnetic fields. *Orthop Trans J Bone Joint Surg*. 1978;2:218.
21. Bergsmann O. Selektive Feldtherapie bei pseudoradikulären Symptomen. In: *Manuelle Medizin, XXI.* Vienna, Austria; 1983.
22. Cameron H, Park YS. An examination of the effects of pulsed magnetic fields on knee swelling following total knee replacement. Presented at the International Congress on Foot and Hand Surgery; 1981; São Paulo, Brazil.
23. Ehrmann W, von Leitner H, Ludwig W. Therapie mit ELF-Magnetfeldern. *Z Phys Med.* 1976; 4:161-170.
24. Evertz U, König H. Pulsierende magnetische Felder in ihrer Bedeutung für die Medizin. *Hippokrates.* 1977;1:16.
25. Shafik A. Effect of magnetic stimulation on the contractile activity of the rectum in dog. *Eur Surg Res*. 1998;30:268-272.
26. Shafik A, el-Sibai O. Effect of magnetic stimulation on the contractile activity of the rectum in humans. *Am Surg*. 2000;66:491-494.
27. Shafik A. Magnetic stimulation: a novel method for the treatment of chronic constipation. *Minim Invasive Ther Allied Technol.* 1998;7:477-481.
28. Shafik A. Penile erection in dogs by magnetic stimulation of the cavernous nerve. *Arch Androl.* 1999;43:247-252.

29. Shafik A, el-Sibai O, Shafik AA. Magnetic stimulation of the cavernous nerve for the treatment of erectile dysfunction in humans. *Int J Impot Res.* 2000;12:137-142.

30. Hainovici N, Negoesen J. Beeinflussung der Kallusbildung unter der Behandlung mit niederfrequenten gepulsten Magnetfeldern. *Therapiewoche*. 1987;30:4619-4631.

31. Pelka RB, de Moliere M. *Migräne, Wetterfühligkeit und Spannungskopfschmerz: Essentielle Linderung durch Magnetwechselfelder?* Notabene Medici; 1989.

32. Watson J, Downes E. Clinical aspects of the stimulation of bone healing using electrical phaenomena. *Med Biol Eng Comput.* 1979;17:261.

33. Tan HL. Economic costs of male erectile dysfunction using a decision analytic model. *Pharmacoeconomics.* 2000;17:77-107.

34. Laumann EO, Paik A, Rosen RC. Sexual dysfunction in the United States. Prevalence and predictors. *JAMA.* 1999;281:537-544.