Research Article

The use of Functional Magnetic Stimulation in the Treatment of Erectile Dysfunction.

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Abstract
A previous study in humans has demonstrated that magnetic stimulation (MS) of the cavernous nerve produced an increase of the intracorporeal pressure and full penile erection. In view of these results, We tested the potential use of this procedure in humans with erectile dysfunction (ED). The study comprised 60 patients with ED (age 39.7±13.555 y). A hand peace was placed over the ventral aspect of the penis followed by FMS chair session. FMS was performed using a stimulation of 40% intensity, 10 Hz frequency, 10s on and 10 s off for 10 minutes duration followed by a stimulation of 40% intensity, 25 Hz frequency, 10s on and 10 s off for 10 minutes duration. In the healthy volunteers, the coil was placed as aforementioned but was not activated. The international index of erectile function showed a significant improvement in erectile function after the procedure.
Keywords: functional magnetic stimulation; erectile dysfunction; impotence; international index of erectile dysfunction; FMS chair; FMS hand peace.

Introduction
The causes of erectile dysfunction (ED) are different and include hormonal, neurogenic, psychological, arterial and venous disorders. Neurogenic disorders are caused by diseases or dysfunctions of the brain and spinal cord, cavernous, pudendal nerves and terminal nerve endings and receptors. The commonest hormonal disorder is diabetes mellitus. Arteriogenic impotence is often a component of systemic arterial disease. Abnormalities in venous flow can be due to a tunica albuginea defect, excessive or enlarged veins, or fibrous replacement of the smooth cavern muscles. Treatment for ED depends on the etiology. Several well-established processes have been developed.

However, the results are dissatisfying in many cases until now (Fishman 1986). Studies on dogs (Shafik 1994) and on patients with ED (Shafik 1996) have demonstrated that extra pelvic cavernous nerve (CN) stimulation effected full penile erection. Also preceding studies in patients with ED have demonstrated that Functional Magnetic Stimulation (FMS) of the CN is believed to be suitable for application in patients with ED and is effective in producing penile rigidity (Shafik et al., 2000). FMS has been used to activate the neuromuscular tissue and magnetic stimulators are applied for neurophysiologic investigations. Motor-evoked potentials were generated from the urinary bladder upon FMS of the cauda equina (Bemelmans et al., 1992).

Neuromodulation of detrusor hyperreflexia could also be achieved by FMS of the sacral roots (Sheriff et al., 1996). FMS produces its effect by creating, according to Faraday's law, an electric field which can stimulate the neuromuscular tissue (Barker et al., 1987).

A study on dogs (Shafik 1998) and another one on human healthy volunteers (Shafik and El-Sibai 2000) have demonstrated that sacral muscle of both the full and the empty rectum effected a significant increase in rectal and vesical pressures and a decrease in the anal pressure. Evacuation of the full rectum using intermittent Magnetic Stimulation (MS) was achieved. FMS was also used for the treatment of patients with constipation due to rectal inertia (Shafik 1998).

The efferent activity of the penis occurs in the 2nd ,3rd and 4th segments of the sacral spinal cord. These sacral nerves, known as erect nerves form three to six district tribes in men. They are united, to form the pelvic nerve that merges into the pelvic plexus. CN, the autonomic nerve of the penis, comes from the pelvic plexus. It moves along the posterolateral side of the prostate to approach the membranous urethra at the 3 and 9 o'clock positions. The nerves on either side proceed forward with medial inclination. They pierce the urogenital diaphragm to enter the corpora cavernosa at the 1 and 11 o'clock positions beneath the symphysis pubis (Shafik et al., 2000).

Materials and Methods

After obtaining Institutional Ethical Committee approval and written informed consent, this study will be conducted on 60 adult male patients with ED aged from 18 to 70 years. They will be allocated into 3 groups (20 patients on each group): Group I (A group): Diabetic patients with ED, Group II (B group): Patients with venogenic ED and Group III (C group): Patients with psychogenic erectile dysfunction. The procedure will be performed without anesthesia and with the subject lying supine. A commercially available magnetic stimulator (TESLA Stym, Functional Magnetic Simulation (FMS), Iskara Medical, Ljubljana, Slovenia) with a FMS hand piece and FMS chair will be used in the study. Every subject will undergo 20 sessions. FMS was performed using a stimulation of 40% intensity, 10 Hz frequency, 10s on and 10 s off for 10 minutes duration followed by a stimulation of 40% intensity, 25 Hz frequency, 10s on and 10 s off for 10 minutes duration. In the healthy volunteers, the coil was placed as aforementioned but was not activated. The international index of erectile function showed a significant improvement in erectile function after the procedure.

Results

Our subjects were evaluated by IIEF questionnaire which is an internationally applicable questionnaire, a multidimensional scale and an effective and validated tool used to evaluate erectile function. It addresses the most relevant aspects of male sexual function, such as erectile strength, orgasm, desire, satisfaction with intercourse, and overall satisfaction. In the present study, response to this procedure showed that about 95% of the patients were either satisfied with the effect of the FMS sessions on their erections or reported improvement of their erections over the last 8 weeks of treatment. There was no significant between before and after treatment in group B regarding the sexual desire domain score, however there were significant difference between before and after the treatment in sexual function domain score in group A and group C.

There was significant difference between before and after the treatment regarding erectile function domain score, orgasmic function domain score, intercourse satisfaction domain score and overall satisfaction domain score. To our knowledge, there no any other previous study discussed the role of FMS in the treatment of the erectile dysfunction or evaluate the results with IIEF except (Shafik et al., 2000) who discussed the effect of magnetic stimulation in increasing the intracorporeal pressure of the penis.

Discussion

This study demonstrates the effectiveness of FMS in the treatment of erectile dysfunction. It seems that FMS has activated the cavernous nerve. The optimal site of the FMS hand piece was found to lie over the ventral of the penis.

FMS produces its effect by creating a magnetic field which, according to Faraday's law, generates an electric field that seems to activate the CN. When a time varying magnetic field is applied close to neuromuscular tissue, the induced electric field creates a current that can stimulate the neuromuscular tissue. The magnetic fields can pass through structures of high resistance like skin, fat and bone (Barker et al., 1987).FMS applicator, as it overlies the ventral of the penis, could stimulate the cavernous nerve and the deep dorsal nerve of the penis. The latter, arising from the pudendal nerve, proceeds forward through the suspensory ligament to lie over the dorsum of penis.

The branches of the cavernous nerve go along the back of the penis in the vicinity of the dorsal nerve of the penis. The dorsal nerve forms the afferent limb of the erectile reflex of the penis by transmitting sensory impulses to the skin of the penis, the glans and prepuce. In addition, it contains efferent autonomic fibers in some species. The physiological significance of these efferent pathways is uncertain. Researchers have postulated that such efferent contributions to the dorsal nerve of the penis control the blood vessels in the skin of the penis or modulate the sensitivity of afferent receptors. Activation of the cavernous nerve by FMS, as noted above, likely causes the smooth muscles that surround the lacunar spaces of the penis and helical arterioles to relax.

Theoretically, electrostimulation of the cavernous nerve, which is autonomic, induces changes in blood flow. Furthermore, Stimulation of the pudendal nerve, which is somatic,

with one-off 10 seconds causes contraction and relaxation of the ischiocavernosus muscle which leads to strength this muscle and increase its vascularity. Neither Shafik et al., 2000 nor any other previous studies discussed the role of FMS chair in the treatment of ED in humans before and many other studies considered Functional Magnetic Stimulation as a conservative, safe, non- invasive and effective intervention for the treatment of stress urinary incontinence by contraction of the pelvic floor muscles with simultaneous inhibition of the antagonistic reflex mechanism for emptying the bladder.

How neuromodulation works is not yet fully understood. FMS induced magnetic field which acts mainly on the membranes of the motor nerves. As a result, the muscle contraction resulting from FMS is most likely caused by depolarization of the motor nerves. Motor nerves that supplies pelvic muscles floor like levator ani and related sphincters. This act as pelvic motor floor exercise.

Conclusion

We can say that FMS is an effective, conservative, non-invasive and safe method in the treatment of erectile dysfunction. Thus, we recommend further studies should be undertaken to comprehensively analyze this option to the other options like medical and surgical options.

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