



# POSTPROSTATECTOMY CONTINENCE AFTER FUNCTIONAL MAGNETIC PELVIC STIMULATION

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**SUMMARY** – Although radical prostatectomy is considered the gold standard for optimal treatment of localized prostate cancer, this radical surgery carries a significant risk of erectile dysfunction and urinary incontinence which can be present as transient or permanent side effects in many patients. We have made significant advances in diagnostic and surgical approach to prostate cancer, using a number of new methods that are becoming increasingly available, resulting in better treatment outcomes. However, we still do not use all the possibilities for the prevention and treatment of these side effects, probably due to their insufficient research, or unclear effectiveness. Functional magnetic stimulation is a method used to treat a large number of diseases, i.e., to alleviate their symptoms and ailments. Its role through pelvic stimulation has been proven in the treatment of incontinence in women, and in our study, we want to determine its role in more detail, primarily in the treatment of urinary incontinence in patients after prostate cancer surgery. In case of positive results, this method may be recommended for wider use in patients with adverse effects of radical prostatectomy.

**Key words:** *Radical prostatectomy; Functional magnetic stimulation; Quality of life; Urinary incontinence; Erectile dysfunction; Pelvic rehabilitation*

## Introduction

Radical treatment of prostate cancer (PCa), regardless of the method chosen, as with many other cancers, carries a significant risk of unwanted functional outcomes. Data on the frequency, intensity and duration of urinary incontinence (UI) and erectile dysfunction (ED) as the two most important side effects of radical prostatectomy (RP) vary considerably in the published literature, depending on the definition, timing and methods of assessment by physician or patient. Yet, they are present in a large number of patients after

PCa surgery, significantly reducing their quality of life (QoL) and overall satisfaction with RP while also adding time and money, as well as additional sick leave for their treatment, which further burdens patients and society in general<sup>1,2</sup>.

There are several treatment options used to reduce or prevent these side effects, from pelvic floor muscle exercises/training and electrostimulation with or without biofeedback, functional magnetic stimulation (FMS), to various medications and compression devices such as penile clamps, but also various surgical procedures, from minimally invasive such as urethral bulking agents to open surgical procedures such as implantation of an artificial sphincter or penile prosthesis. So, many different methods indicate the complexity of these problems, but also the lack of universal, effective methods of treatment of postprostatectomy ED

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and UI. Furthermore, although improvement of our knowledge, as well as improvement in surgical technique will reduce this side effects, due to the increased number of RPs performed worldwide, an increase in their incidence is expected<sup>3</sup>.

### Functional Magnetic Stimulation

Functional magnetic stimulation is considered the most common noninvasive procedure for the treatment of UI with proven efficacy, especially in combination with electrostimulation, as it has been shown to have a significant positive effect on early return of urinary continence after RP by increasing pelvic floor strength and endurance<sup>4-8</sup>. However, this method must be well understood, learned, and practiced regularly, moreover, it requires active participation of patients, which can be a challenge for a significant number of them, who simply cannot master or even use it for various reasons.

Stimulation of nerves by magnetic field began in the early 1960s, first in animals and then in humans, and then, mainly under the influence of technical improvement, i.e., progression from a single stimulation generator to a continuous one, gradually increased its application<sup>9</sup>. FMS is used today for many different conditions and diseases or their symptoms. Stimulation of the central and peripheral nervous system reduces and alleviates acute musculoskeletal pain, degenerative rheumatism, neuritis, nerve paresis and paralysis, neuropathy, posttraumatic conditions, helps rehabilitation after immobilization, sports injuries, stroke and postoperative conditions, as well as faster recovery of fractures, but also wound healing<sup>10</sup>. It was first approved in the United States in 1998 for stress, urge, and mixed UI, and has been used for years primarily to treat stress incontinence in women<sup>11</sup>.

The basic principle of FMS is to stimulate the patient's striated pelvic floor muscles and smooth muscles of the bladder, urethra and even blood vessels, activate motor and sensory fibers, and improve microcirculation. Magnetic stimulation is considered to have an even greater effect due to deeper penetration into tissue compared to electrical stimulation. It is also a noninvasive, relatively painless, safe and simple method, without side effects and can be performed as an outpatient procedure without the need to undress the patient as the magnetic field can pass through clothing<sup>12</sup>. The role of pelvic floor FMS has already been investigated in patients with UI after RP, al-

though the number of published studies on this topic is very limited, but they have generally shown a beneficial effect of FMS alone or in combination with other treatment modalities for UI, mostly shortening the time from surgery to postoperative urinary continence, by increasing maximal urethral closure pressure, reducing or inhibiting detrusor overactivity, and increasing functional bladder capacity<sup>13,14</sup>. Furthermore, the reduction in pad use and pad test weight averaged about 50%, which gives additional reasons to recommend this method<sup>15-18</sup>. Therefore, we decided to conduct this study to investigate and evaluate the role of FMS in our patients after RP.

### Study protocol

In this double blind, randomized study, we will include patients who had RP (open, laparoscopic, or robotic) for clinically localized PCa at the Department of Urology, Zagreb University Hospital Center. Inclusion criterion is UI after RP. Exclusion criteria are previous history of UI or its treatment, previous history of prostate surgery, known anatomic pelvic malformations, previous history of pelvic surgery or trauma, known neuromuscular disease or complications after prostatectomy that may affect UI. This study has been approved by the Ethics Committee of our institution.

The study protocol will be clearly explained to the interested and eligible patients, who will sign an informed consent to accept participation in the study. Patient data (age, prostate specific antigen values, body mass index, digital rectal exam and biopsy findings, date and type of surgery (possible complications), histopathologic findings, and length of hospital stay and catheterization) will be collected.

After discharge from the hospital, patients will be contacted and treated in our outpatient clinic twice a week for a month (a total of 8 treatments) using a Tesla Care device (IskraMedical d.o.o., Ljubljana, Slovenia), which is routinely used to treat different types of incontinence using different protocols preset or customized by medical staff. Patients will be randomized in two groups using free randomization software. The first group will have an FMS from the electromagnetic generator under the seat, while in the other, control group we will use an external FMS unit without contact between electromagnetic generator and the pelvis (sham treatment). In both groups, patients will be comfortably seated in an FMS chair with a magnetic

field generator and will have the same FMS protocol with the same duration (the same visual and sound conditions created by the generator and control unit) to make group research as similar as possible. Before treatment, patients will be informed on the procedure, including sensations, i.e., contractions in the pelvis that they may feel. Stimulation will be performed at a frequency of 10 Hertz for 10 minutes, followed by a break of 1 minute, then second treatment at 50 Hertz for 10 minutes. The intensity of the magnetic field will be chosen individually to avoid unpleasant sensations during the procedure. The maximal power of the magnetic field will be 0.4 Tesla. The stimulation protocol may change/adjust during the study. In each session, adherence to treatment and possible adverse effects of therapy will be identified and recorded. Patient safety and health will be a priority in this study, so in case of adverse effects, the principal investigator will decide whether to continue the study for selected patients.

Urinary continence status will be evaluated before each treatment and 1, 3, 6 and 12 months after it, using the number of pads *per day* and the International Consultation on Incontinence Questionnaire (ICIQ-UI SF), a simple and short questionnaire for evaluation of the frequency and severity of UI, as well as its influence on patient QoL<sup>19-21</sup>. To assess QoL, we will use the Personal Wellbeing Index and World Health Organization Quality of Life (WHOQOL-BREF) questionnaire. These questionnaires have been translated and validated for use in the Croatian language.

### Statistical analysis

Data will be collected in a special database created for this study. Statistical analysis will be done using the STATISTICA 6.1 program (StatSoft Inc., Tulsa, OK, USA). Quantitative patient data will be described by descriptive statistics (mean or median and standard deviation or range, respectively, depending on the normality of the distribution for quantitative variables). Qualitative patient data will be described by frequencies tables (absolute and relative (%) frequencies).

Statistical difference between the two groups before each treatment and 1, 3, 6 and 12 months after it will be tested by factorial analysis of variance (ANOVA). The level of statistical significance established will be the usual one (95%); therefore, statistically significant differences will be considered when p values are less than 0.05.

## Discussion

Most patients eventually recover continence and achieve relatively good results after RP, but it is not the same whether they need 2, 4, 6, 12 months or even more to do so. If we can help them reduce that time, i.e., speed up their recovery, especially if we can do it with simple and noninvasive methods. Thus, we should offer them to our patients for several very important reasons, from improving QoL to health economy perspective. The results of this study will help us evaluate the role of FMS in the treatment of UI after RP. In case of positive results, this technique can be recommended for more frequent use.

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#### Sažetak

### POSTPROSTATEKTOMIJSKA KONTINENCIJA NAKON FUNKCIONALNE MAGNETSKE STIMULACIJE ZDJELICE

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Iako se radikalna prostatektomija smatra zlatnim standardom za optimalno liječenje lokaliziranog raka prostate, ova radikalna operacija nosi značajan rizik od erektilne disfunkcije i urinarne inkontinencije koje su prisutne kao prolazne ili trajne nuspojave kod velikog broja bolesnika. Napravili smo značajan napredak u dijagnostičkom i kirurškom pristupu raku prostate primjenjujući niz novih metoda koje su sve dostupnije, što je rezultiralo boljim rezultatima liječenja. Međutim, još uvijek nedovoljno rabimo sve mogućnosti za prevenciju, ali i liječenje ovih nuspojava, vjerojatno zbog njihove nedovoljne istraženosti, odnosno nejasne učinkovitosti. Funkcionalna magnetska stimulacija je metoda koja se primjenjuje za liječenje velikog broja bolesti, odnosno za olakšavanje njihovih simptoma i tegoba. Njezina uloga kroz stimulaciju mišića zdjelice je dokazana u liječenju inkontinencije kod žena, a u našem istraživanju želimo detaljnije utvrditi njezinu ulogu, prvenstveno u liječenju urinarne inkontinencije u bolesnika nakon operacije raka prostate. U slučaju pozitivnih rezultata ova se metoda može preporučiti za širu primjenu u bolesnika s neželjenim posljedicama radikalne prostatektomije.

**Ključne riječi:** *Radikalna prostatektomija; Funkcionalna magnetska stimulacija; Kvaliteta života; Urinarna inkontinencija; Eretilna disfunkcija; Rehabilitacija zdjelice*