

DOI: <https://doi.org/10.17816/uroved63508>



Biofeedback in the treatment of patients with urine incontinence after radical prostatectomy

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The review article is devoted to the application of the biofeedback in the treatment of patients with urinary incontinence after radical prostatectomy. The data on the mechanism of urinary continence in men and its damage during surgery are presented, the pathogenetic basis of the therapeutic effect of pelvic muscle training in this patients is highlighted. The analysis of the main russian and foreign clinical studies on the use of the biofeedback in patients with urinary incontinence after prostatectomy has been carried out. It is indicated that biofeedback increases the effectiveness of conservative treatment of urinary incontinence, however the even wider use of this method of treatment is limited by the lack of standard protocols for training pelvic muscles under the control of biofeedback.

Keywords: urinary incontinence; pelvic floor muscle training; biofeedback; radical prostatectomy.

To cite this article:

Krotova NO, Ulitko TV, Kuzmin IV, Al-Shukri SKh. Biofeedback in the treatment of patients with urine incontinence after radical prostatectomy. *Urology reports (St. Petersburg)*. 2021;11(1):69-77. DOI: <https://doi.org/10.17816/uroved63508>

Received: 19.01.2021

Accepted: 16.03.2021

Published: 23.03.2021

DOI: <https://doi.org/10.17816/uroved63508>

Метод биологической обратной связи в лечении пациентов с недержанием мочи после радикальной простатэктомии

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Обзорная статья посвящена применению метода биологической обратной связи в лечении пациентов с недержанием мочи после радикальной простатэктомии. Приведены данные относительно механизма удержания мочи у мужчин и его повреждения во время операции, освещены патогенетические основы лечебного эффекта тренировок тазовых мышц у данной категории больных. Проведен анализ основных отечественных и зарубежных клинических исследований, посвященных применению метода биологической обратной связи у пациентов с недержанием мочи после простатэктомии. Указано, что биологическая обратная связь повышает эффективность консервативного лечения недержания мочи, однако еще более широкое распространение данного метода лечения ограничивает отсутствие единых протоколов проведения тренировок тазовых мышц под контролем биологической обратной связи.

Ключевые слова: недержание мочи; тренировка мышц тазового дна; биологическая обратная связь; радикальная простатэктомия.

Как цитировать:

Кротова Н.О., Улитко Т.В., Кузьмин И.В., Аль-Шукри С.Х. Метод биологической обратной связи в лечении пациентов с недержанием мочи после радикальной простатэктомии // Урологические ведомости. 2021. Т. 11. № 1. С. 69–77. DOI: <https://doi.org/10.17816/uroved63508>

Prostate cancer (PC) ranks second in the overall structure of cancer morbidity in the male population, which accounts for 15% of all neoplasms in men [1]. The use of modern methods of early diagnostics of PC increases its detection rate in the early stages, when radical methods of treatment can be applied [2]. Radical prostatectomy (RPE) is the gold standard of treatment in localized PC. Since the introduction of RPE in clinical practice, PC surgery has focused mainly on improving the surgical technique. The results of using of two- and three-dimensional laparoscopic techniques, robot-assisted surgery, and nerve-sparing and Retzius-sparing techniques improve the functional outcomes of treatment [3, 4].

Urinary incontinence, along with erectile dysfunction, is becoming the most common complications of RPE [5–7]. The estimated frequency of urinary incontinence after RPE ranged from 0.8% to 88%, but it is approximately 20% in most studies [5]. Involuntary excretion of urine is a significant social, hygienic, and psychological problem that leads to asthenia, anxiety, and depression [8]. This is important given the current 10-year survival rate after RPE exceeding 90%. Most studies have indicated that in 70% of patients, the urinary continence mechanism is restored within 3 months after surgery; however, there is still a high proportion of patients whose urinary incontinence persists in the future [4]. Factors that increase the risk of urinary incontinence after RPE include patient's older age, reduced performance status, initial dysfunction of the lower urinary tract, weakness of the pelvic floor muscles, as well as history of surgical interventions in which the sphincter mechanism is affected (such as transurethral resection, laser ablation, laser vaporization, and enucleation of the prostate gland) [9–12].

Two anatomical structures are known to be involved in the mechanism of urinary continence in men, the proximal (preprostatic) urethral sphincter and the distal urethral sphincter. The proximal sphincter consists of smooth muscle fibers that enclose the prostatic urethra from the bladder neck to the seminal hillock. The distal sphincter consists of internal striated and smooth muscle fibers and external paraurethral striated muscle fibers. The distal sphincter encloses the prostatic urethra below the seminal hillock to the membranous urethra. In the course of RPE, the proximal sphincter is removed, so the distal sphincter remains the only structure involved in urinary continence.

The distal urethral sphincter is mainly represented by striated muscle fibers with minor involvement of smooth muscles. Voluntary muscle fibers provide tonic contraction of the sphincter at rest and are designated as type I muscle fibers (slow or tonic) [13]. Striated fibers of the external paraurethral muscle (*m. pubococcygeus*) are part of the musculus levator ani (*m. levator ani*) and

are classified as fast-contracting muscle fibers (type II). They are necessary for strong short-term contractions in response to a sharp increase in intra-abdominal pressure, which ensures the continence of urine in the bladder [14]. During RPE, damage to the muscle fibers of the distal urethral sphincter and/or disruption of its innervation can occur, which leads to urinary incontinence. Urinary incontinence after RPE is considered one of the variants of stress incontinence [15].

At present, a significant number of methods for correcting urinary incontinence after RPE, both conservative and surgical, have been proposed. However, conservative non-drug therapy can be considered a priority in the treatment of such patients, since it is the most accessible, safe, and effective treatment. Nowadays, the main methods of conservative non-pharmacological treatment of urinary incontinence in patients after RPE are behavioral therapy, pelvic floor muscle training (PFMT), electrical stimulation of pelvic muscles, biofeedback (BFB), and magnetotherapy. These options can be used both independently and in combination [16, 17].

The efficiency of PFMT in the treatment of stress and mixed forms of urinary incontinence in women has been proven in many studies, including randomized multicenter studies [18, 19]. However, there is much less research on the use of pelvic exercise to improve urinary incontinence in men. However, the pathogenetic mechanisms providing the efficacy of PFMT in women suggest a similar clinical effect regardless of the patient's gender [20, 21]. Damage to the muscle fibers of the distal urethral sphincter is associated with their denervation, leading to atrophy of the denervated fibers. In PFMT, viable nerve fibers are able to stimulate reinnervation, and fast-contracting fibers are transformed into tonic slow-contracting ones, which influence the functional integrity of the pelvic floor [22]. Unlike nerves, muscles have a high potential for regeneration, and special training for the pelvic muscles plays an important role in this process [23].

During PFMT, in patients with urinary incontinence after RPE, it is necessary to strengthen both slow-contracting muscle fibers to increase the tone and endurance of the pelvic muscles (type I fibers) and fast-contracting muscle fibers to ensure a quick muscle response to an increase in intra-abdominal pressure (type II fibers) [24]. Therefore, it is recommended to include fast strong voluntary contractions of *m. levator ani* in the set of exercises, lasting no more than 1 s (20–50 contractions per day), and static contractions of *m. levator ani* keeping it in a contracted state for at least 6 s with a gradual increase with each time. In addition to these types of muscle contractions, some training complexes include the so-called intense contractions, which are achieved by a smooth gradual contraction of *m. levator ani* for a certain time up to the maximum possible level [25].

Pelvic floor muscle exercises are recommended for all patients with a history of RPE for early prevention of urinary incontinence after urethral catheter removal [26]. However, there is a problem of correctness of these exercises, as 40%–60% of the patients are unable to contract pelvic floor muscles in isolation [27]. Instead of contracting the *m. levator ani*, patients strain antagonistic muscles, namely, the rectus abdominis muscle, gluteal muscles, and femoral muscles, further increasing the intra-abdominal pressure. Obviously, such exercises are not only ineffective, but can also contribute to the progression of urinary incontinence. In this regard, teaching patients to perform the exercises correctly appears very urgent, for which the BFB method was proposed. When applying the BFB method, by means of electronic devices through an external feedback loop, a person receives instantly and continuously the information about the state and changes of certain own physiological processes, in particular, about the contraction of the pelvic muscles. Thus, through BFB, in the course of training, patients can control the correctness of the exercise, and the doctor gets the opportunity to evaluate the work of various muscle groups. The main task of BFB in the treatment of patients with urinary incontinence is strengthening of various muscle bundles in the *m. levator ani*, which increases the intra-urethral pressure in response to an increase in intra-abdominal pressure [28, 29].

To provide BFB in men with urinary incontinence, electromyographic (EMG, anal and superficial) and manometric sensors are used. Some BFB devices record the contraction of additional muscles, for example, the muscles of the abdomen, buttocks, and thighs. This helps avoid the contraction of additional muscles and helps achieve maximum efficiency when performing exercises for the pelvic muscles [30]. Treatment using BFB has no side effects. Training is allowed even in the presence of sufficiently serious concomitant diseases that are contraindications to surgical treatment for urinary incontinence [31].

Studies of the efficiency of PFMT in combination with BFB in men with urinary incontinence were started in the late 1990s. In a study by Mathewson-Chapman [32], 53 patients with urinary incontinence after RPE were randomly distributed in the PFMT training group and control group. Patients of the main group received instructions to perform PFMT with the use of BFB; the training to perform exercises was conducted three times a week for 12 weeks. Patients of the control group were not trained using BFB. Although patients in both groups demonstrated a decrease in the severity of urinary incontinence, this study recommends using the capabilities of the BFB method in training the correct performing PFMT.

To date, considerable experience has been accumulated in the use of BFB in the treatment of urinary

incontinence after RPE. Alyaev et al. [33] published the results of a study of PFMT efficiency in combination with BFB in 55 patients who underwent RPE with urinary incontinence that occurred immediately after surgery. The average age of the patients was 64 (55–74) years. After 6 months of training, urinary incontinence completely disappeared in 10 (18.2%) patients, and 15 (27.3%) patients noted an improvement. At the same time, no changes were registered in 28 (50.9%) patients. During this period, an artificial urethral sphincter was installed in 2 (3.6%) patients. In patients with a persistent skill of isolated contractions of the pelvic muscles, the average recovery time for urinary continence was 5 months, and in patients without this skill, it was 12 months.

Glybochko et al. [34] evaluated the efficiency of two-channel EMG BFB in 87 patients with urinary incontinence after RPE. EMG channels 1 and 2 showed the activity of the pelvic muscles and muscles of the anterior abdominal wall, respectively. The skill of isolated contraction of the pelvic muscles with minimal involvement of the abdominal muscles was acquired by 42 (48.3%) patients following 2–4 sessions of training. The remaining 45 (51.7%) patients required weekly use of two-channel BFB for the entire treatment period to perform PFMT correctly, and 18 (40%) of 45 patients with urinary incontinence after RPE, who underwent BFB training, achieved recovery or improvement. The average time interval to achieve improvement in urinary continence in these patients was 9.5 months. An improvement in urinary continence was achieved in 29 (69%) of 42 patients who mastered the skill of isolated contractions of the pelvic muscles.

Demidko et al. [35] used the BFB method in 142 patients with urinary incontinence who underwent a nerve-sparing RPE. The duration of PFMT under the BFB control ranged from 1 to 13 months. During this time, 37 (26.1%) patients were able to retain urine completely, and 31 (21.8%) patients improved their condition, which was manifested in a decrease in the number of incontinence episodes and a decrease in the number of pads used. No improvements were noted in 69 (48.6%) patients, 2 (1.4%) patients underwent sub-urethral loop repair, and in 3 (2.1%) patients, an artificial urethral sphincter was installed.

Vinarov et al. [36] analyzed the results of exercise for the pelvic muscles under BFB in 251 patients with urinary incontinence after open, laparoscopic, and robot-assisted RPE. The duration of urinary incontinence at the start of training was 5.8 (0.5–39.5) months. In that study, 204 (81.3%) patients acquired the skill of isolated contraction of the pelvic muscles through the BFB method. To perform the exercises correctly, 47 (18.7%) patients required regular (1–2 times a month) training under BFB control. In the group of patients with the fixed skill of isolated contractions of the pelvic muscles and its independent use, better functional results were noted

compared with patients who required hardware support for training.

In 2019, the results of the use of portable BFB devices in patients with urinary incontinence after RPE were published. All patients were distributed into the study group ($n = 20$) and control group ($n = 20$). The patient groups were comparable in terms of age, duration, and severity of involuntary urine excretion. In the main group, PFMT was performed using a portable BFB device, and in the control group, BFB was not applied. Portable BFB devices were handed out, and the patients used them for each exercise of the pelvic muscles. The study revealed a significantly greater efficacy in the treatment of incontinence in the main group compared with the control group [37].

Ribeiro et al. [38] published the results of a comparative study of PFMT efficiency under BFB control in 73 patients with urinary incontinence after RPE; 36 patients included in the treatment group performed PFMT under BFB control (once a week) for 3 months, and 37 people from the control group only received PFMT. Treatment was started immediately after removal of the urethral catheter. The result of treatment was considered positive when urinary continence was restored, and the severity of urinary incontinence was determined by a 24-h pad test. The study showed significantly better results in the treatment group than in the control group. By month 12 after RPE, urinary continence was restored in 96% of the patients in the treatment group and in 75% of patients in the control group ($p = 0.028$). The authors concluded that early initiation of treatment is justified, as it significantly accelerates recovery of urinary continence after RPE.

Kim et al. [39] examined the efficiency of BFB in 83 patients with urinary incontinence after robotic-assisted RPE and concluded that the efficiency of BFB is higher in patients aged >65 years than in younger patients.

Thus, studies have proved the feasibility of using BFB for teaching patients to perform PFMT correctly. A longer training period in a number of patients is apparently associated with age-related changes in the pelvic muscles, presence of concomitant diseases, initial severity of symptoms, and adherence to this type of treatment. PFMT in combination with BFB as an additional source of information on functioning of the perineal muscles increases the training efficiency and appears to be an effective method of treating urinary incontinence after RPE.

Although most publications indicate positive results of BFB therapy, its efficiency is difficult to assess. This is due to the lack of a standard BFB technique and unified criteria for evaluating the efficiency of treatment, which makes it impossible to compare the results of different studies [40]. For these reasons, some publications

cannot confirm the superiority of PFMT in combination with BFB over other conservative methods of treatment. Thus, Strączyńska et al. [41] performed a systematic review, but did not find a significant increase in the efficiency of the treatment of urinary incontinence after RPE with the use of BFB. The authors indicated that this result was caused by an insufficient number of studies analyzed, different methods of assessing the effect, and dissimilarity of the patients monitored. Anderson et al. [42] published the results of a meta-analysis of efficiency of various conservative treatment methods for urinary incontinence after RPE, namely, PFMT with and without BFB, electromagnetic and magnetic stimulation of the pelvic muscles, and similarly come to an unambiguous conclusion on the advantage of one or another treatment method. MacDonald et al. [43] conducted a meta-analysis of 11 clinical studies of the efficiency of various conservative treatment options for urinary incontinence after RPE, which included 1028 men. The authors noted that the use of BFB increases the efficiency of PFMT in the first 1–2 months of treatment, but BFB did not influence the therapeutic effect of training.

Mariotti et al. [44] examined the efficiency of the combined use of PFMT under the control of BFB in combination with electrical stimulation of the pelvic muscles. A total of 120 patients with urinary incontinence after RPE were under follow-up in the study. Group 1 included 60 patients whose treatment was started 14 days after removal of the urethral catheter. Group 2 also consisted of 60 patients, but their treatment was performed 12 months after RPE. The treatment regimen in both groups was equal. The study results demonstrated the treatment efficiency, regardless of the time of its initiation. Moreover, the best clinical results were achieved with an earlier start of therapy.

Currently, in Russia, the BFB method was introduced widely in clinical practice for the treatment of urinary incontinence and pelvic floor muscle failure in women. The BFB therapy in men for the treatment of urinary incontinence after RPE has so far been performed in a few centers. However, in recent years, interest in this method of treatment has significantly increased, which is associated not only with its efficiency, but also with an increase in the number of RPE performed and the development of new equipment to provide BFB. One of the new devices for BFB therapy is the Russian apparatus "Uroproktokor" ("In-Vitro," St. Petersburg). In the treatment of men with urinary incontinence, a rectal EMG sensor is used, which records bioelectrical signals from the pelvic floor muscles during exercise. A wide range of specially developed motivational programs can increase significantly the patient's adherence to treatment and thereby increase its efficiency.

Thus, available data recommend inclusion of BFB in the complex treatment of patients with urinary

incontinence after RPE. The use of BFB increases the efficiency of PFMT, contributing to the patient's training in the correct execution of contractions. However, there are certain difficulties in comparing the results of different clinical studies due to the absence of uniform standards for training and BFB. For this purpose,

it appears expedient to develop general training protocols with clear definition of frequency, time characteristics of muscle contraction and relaxation, number of repetitions per day, etc. These standards will contribute to an even greater widespread use of this treatment method.

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