Effectiveness of Biofeedback Therapy as Conservative Choice for Management of Female Stress Urinary Incontinence

Abstract

The aim of this study is to evaluate the efficacy of biofeedback (BF) therapy in females with stress urinary incontinence by a systematic review of available literature database.

Materials and methods. A search of the MEDLINE database in order to find articles related to biofeedback therapy for treating incontinence. The keywords which were used to search the database were: "biofeedback", "women", "stress urinary incontinence". Analyses included full-length, peer-reviewed articles reporting on outcomes of treatment of stress urinary incontinence (SUI) using BF in 18-year-old women and older, from any country, treated in any care setting. The inclusion criteria were that it was an original research, not older than five years and written in English.

Results. The search of the database yielded a total of 123 articles. Further analysis determined that 32 articles were suitable with respect to this study’s search criteria. Finally, the analysis included 5 articles. The studies are from different parts of the world: Egypt, Poland, China, Malaysia and Japan. Two articles are from 2013 and 2015, and one was published in 2016. Three studies evaluated the efficacy of biofeedback therapy (BF therapy) versus self-performed Kegel exercises, and two studies compared biofeedback therapy with electrical stimulation.

Conclusion. Although almost all studies (4 of the 5 analysed) report a positive impact of biofeedback therapy in treating SUI, further research on a more homogeneous group, employing standardized protocols, should be conducted in the future.
Introduction

Urinary incontinence (UI) is a considerable psychological and physical morbidity a millions people worldwide suffer from today (1). It is estimated that the prevalence is between 25% and 45% (2), and it increases with age. It occurs twice more often in women than in men: 13.1% versus 5.4% (3), until the age of 80, after which the prevalence is equal for both genders (4).

The International Continence Society (ICS) defines urinary incontinence as the complaint of involuntary leakage of urine (5, 6) and suggests a classification according to the presence of symptoms and pathophysiological mechanisms of occurrence.

The most prevalent form of urinary incontinence among women, in 50% of cases, is stress incontinence (7, 8). SUI is the most common type of incontinence in women (9-12), and occurs due to increased intra-abdominal pressure during sneezing, coughing, running, laughing or exertion of some greater physical effort (7, 9). SUI affects all age groups, and occurs most commonly in women between 15 and 64 years of age (10). It is a considerable medical and social problem which reduces quality of life, especially in younger women (7), because of the stigma which still exists.

Women suffering from UI rarely seek medical support, which is especially prominent in Europe where 75% of women never sought any treatment (2), which confirms that urinary incontinence is still a taboo topic. Older women still think that UI is a normal physiological state related to the consequences of aging (5), while others believe that surgery is the only available treatment option.

As a consequence, local candida infection, cellulitis, skin irritation, insomnia and fatigue due nocturia may occur (5). Furthermore, self-image dysfunction, avoidance of social activities, traveling, recreation, and interpersonal and sexual dysfunction often occur due to embarrassment. Depression and anxiety often accompany urinary incontinence (5, 13).

Pathophysiology of Urinary Incontinence

The pelvic floor is a complex, three-dimensional mechanical system which consists of several components. The anatomical structures responsible for supporting the pelvic floor are the bony pelvis and endopelvic fascia, pelvic viscera, pelvic diaphragm, urogenital diaphragm, and levator ani muscles (14, 15).

Urine continence is defined as the ability to retain urine in the urinary bladder between episodes of voluntary micturition. Continence depends on the coordinated activity of the central and peripheral nervous system, urinary bladder muscles (detrusors) and anatomical relations between the neck of the urinary bladder and the urethra. When detrusors cannot retain urine inside the urinary bladder due to weakened function, and a patient cannot affect micturition voluntarily since urinary leakage occurs without the patient’s awareness of it, then we can conclude that it is a case of incontinence. Multiple factors can cause incontinence, such as hormonal therapy, menopause, weakened pelvic muscles due to childbirth, some drugs, infections, surgical procedures undertaken on the genitourinary tract, nerve damage, BMI above 30 (5, 10, 16), and sport activities which require frequent jumping (16).

Treatments for UI

Treatment for UI includes surgery and conservative methods, and depends on the type of incontinence, seriousness of the problem and causes. Conservative methods are recommended as a first line of treatment in the management of stress, urge (7) and mixed UI (17). The available non-surgical, conservative treatment methods include lifestyle modification (a voiding diary, refraining from smoking, weight loss), Kegel exercises (exercises to strengthen the tone and contraction of pelvic floor muscles - PFM), behavioural interventions (changing behaviour to eliminate or minimize the problem, bladder training), biofeedback (use of urethral, vaginal or rectal sounding for creating visual or auditory signals when pelvic muscles are contracted), electrical stimulation and a combination of several different methods (11). Kegel exercises with biofeedback (4) or electrical stimulation (8, 18) and weighted vaginal cones (18) are usually recommended.

Non-surgical treatment for UI is effective, cheap, and easy to use in case of a milder stage of incontinence with minimal side effects. All these methods can be used in parallel with surgical methods.
Biofeedback

Biofeedback (BF) is a technique by which a patient can affect a certain physiological function by using signals from their own body, and not just those under the control of the “voluntary” nervous system, but also those under the control of the “involuntary”, that is, the autonomic nervous system. Patient education on using BF requires more time, but the benefits are long-term because the patient becomes much more responsible when it comes to performing exercises when there is an objective medical finding (10). Also, BF is a non-invasive procedure in contrast with surgical treatment and it is the first option for the treatment of SUI in many cases (8).

The aim of this systematic review is to examine the effectiveness of BF therapy for SUI in women.

Methods

In conducting this systematic review, we searched the MEDLINE (via PubMed) database for relevant articles that investigated the effectiveness of biofeedback therapy for women with stress urinary incontinence (SUI). The keywords used to search the database were: “biofeedback”, “women”, “stress urinary incontinence”. For better filtering of results, the terms were placed in quotation marks. The selection criteria included the following:

1. full-length, peer-reviewed articles reporting on outcomes of therapy for SUI using BF in conjunction with other behavioural techniques (Kegel exercises, trans-vaginal electrical stimulation)
2. studies with 18-year-old female participants and older, from any country, affected by SUI, and treated in any care setting (home, hospital, outpatient department)
3. only original research published within the last 5 years, reporting on human subjects, and written in English was included
4. empirical studies conducted using qualitative or qualitative methods were excluded
5. empirical studies including women in the post-partum period, postoperative period, pregnant women, women with neurological disorders and men were excluded
6. unpublished studies and abstracts were excluded.

The selection criteria are shown in Table 1.

During a search of the database by keywords in March 2017, 123 articles were found in total. Further analysis found that 32 articles matched the in-
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A systematic review of literature yielded 5 articles which matched the selection criteria for a more detailed analysis. Only one study included a double-blind test. The studies are from different parts of the world: Egypt, Poland, China, Malaysia and Japan. Two articles are from 2013 and 2015, and one was published in 2016.

The analysis of the articles, description and aims of the research, methodology and results obtained are given in Table 2.

### Table 1. Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>SELECTION CRITERIA</th>
<th>INCLUSION</th>
<th>EXCLUSION</th>
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<tbody>
<tr>
<td>ARTICLE CATEGORY</td>
<td>Original research</td>
<td>Systematic review</td>
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<td>Review article</td>
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<td>Editorial</td>
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<tr>
<td>KEYWORDS</td>
<td>“Biofeedback”</td>
<td>Postpartum</td>
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<td></td>
<td>“Women”</td>
<td>Postoperative</td>
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<td>“Stress urinary incontinence”</td>
<td>Pregnant women</td>
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<td></td>
<td></td>
<td>Neurological disorders</td>
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<tr>
<td>DATE OF PUBLISHING</td>
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<td>Before 2012</td>
</tr>
<tr>
<td>LANGUAGE</td>
<td>English</td>
<td>All others</td>
</tr>
</tbody>
</table>

### Results

A systematic review of literature yielded 5 articles which matched the selection criteria for a more detailed analysis. Only one study included a double-blind test. The studies are from different parts of the world: Egypt, Poland, China, Malaysia and Japan. Two articles are from 2013 and 2015, and one was published in 2016.

The analysis of the articles, description and aims of the research, methodology and results obtained are given in Table 2.

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**Figure 1. Flowchart of search process and selection of articles**
Table 2. Characteristics of the selected studies

<table>
<thead>
<tr>
<th>Author / Year Country</th>
<th>Title</th>
<th>Description and Purpose of Research</th>
<th>Results</th>
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</thead>
<tbody>
<tr>
<td>Hirakawa et al / 2013 Japan (7)</td>
<td>Randomized controlled trial of pelvic floor muscle training with or without BF for urinary incontinence</td>
<td>To compare the effects of pelvic floor muscle training with or without BF</td>
<td>Duration of research: 12 weeks N1=19 (Kegel exercises + biofeedback) N2=20 (Kegel exercises)</td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>A) Kings Health Questionnaire (KHQ) and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)</td>
<td>A) KHQ N1 = p&lt;0.05 N2 = p&lt;0.05 ICIQ-SF N1 = p&lt;0.05 N2 = p&lt;0.05</td>
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<td></td>
<td>B) Pad test</td>
<td>B) No significant differences between the two groups</td>
<td></td>
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<tr>
<td></td>
<td>C) A voiding diary</td>
<td>C) N1 p=0.054 N2 p&lt;0.05</td>
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<tr>
<td></td>
<td>D) Measurement of pelvic floor muscle strength by perineometry</td>
<td>D) N1 p&lt;0.00 N2 p&lt;0.01</td>
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<tr>
<td>Terlikowski / 2013 Poland (10)</td>
<td>Transvaginal electrical stimulation with surface EMG biofeedback in managing stress urinary incontinence in women of premenopausal age: a double-blind, placebo-controlled, randomized clinical trial</td>
<td>To evaluate the results of conservative treatment using transvaginal electrical stimulation with biofeedback (TVES + BF)</td>
<td>Duration of research: 16 weeks N1=64 (TVES + BF) N2=29 (Placebo TVES + BF)</td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
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<tr>
<td></td>
<td>A) Pad test (pads were weighed before and after 6 hours of use, except for the pad used during nightly sleep, which could be used all night)</td>
<td>A) 0 week N1, N2 p=0.324 8 week N1 p=0.022 16 week N1 p=0.024</td>
<td></td>
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<tr>
<td></td>
<td>B) Urodynamic test</td>
<td>B) No significant difference was found between the groups in urodynamic data before and after treatment</td>
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<td></td>
<td>C) Incontinence quality of life questionnaire (I-QOL)</td>
<td>C) 0 week N1, N2 p=0.241 8 week N1 p=0.004 16 week N1 p&lt;0.001</td>
<td></td>
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</tbody>
</table>

*p<0.05 was considered statistically significant
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</table>
| **Ibrahim et al / 2015 Egypt (22)** | Efficacy of BF-assisted pelvic floor muscle training in females with pelvic floor dysfunction | To evaluate the efficacy of BF with Kegel exercises  
Duration of research: 12 weeks  
N1=24 (Kegel exercises + BF in clinical environment)  
N2=23 (Kegel exercises in home environment) | 
Methodology  
A) Pelvic floor questionnaire (PFQ)  
B) Vaginal manometry (VM) |
| *p<0.05 was considered statistically significant |
| *Ong et al / 2015 Malaysia (23)** | Using the Vibrance Kegel Device with pelvic floor muscle exercise for stress urinary incontinence: a randomized controlled pilot study | To evaluate the effectiveness of Kegel exercises performed with a new biofeedback device, compared to Kegel exercises alone  
Duration of research: 16 weeks  
N1 = 19 (Kegel exercises)  
N2 = 21 (Kegel exercises + BF) | 
Methodology  
A) Australian pelvic floor questionnaires (APFQ)  
B) Modified Oxford Scales for pelvic floor muscle strength (MOS) |
| There were no significant differences between the groups at baseline, except for the total urinary score (p=0.045) |
| *p<0.05 was considered statistically significant |
The analysis of five different studies, conducted all over the world and published in the past 5 years, was carried out. The studies investigated the effects of BF therapy on urinary incontinence. All studies included women (n=326) suffering from urinary stress incontinence. Three studies evaluated the efficacy of biofeedback therapy (BF therapy) versus self-performed Kegel exercises (7, 22, 23), and two studies compared biofeedback therapy with electrical stimulation (10, 24).

In 2013, Hirakawa et al. compared the effects of pelvic floor muscle training with or without BF. A total of 39 participants with SUI were randomized into two groups: Kegel exercises with BF (KE + BF) or without BF (KE). By means of the King’s Health Questionnaire (KHQ) and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), they measured quality of life as the primary outcome. A voiding diary, 1-h pad test and manometry were used to get an insight into secondary outcomes.

The difference between the primary and secondary outcomes was assessed before and after 12 weeks of exercise training. The study statistically showed that Kegel exercises, with or without BF, significantly affect the improvement of subjective symptoms (improved quality of life (p<0.05)) and objective symptoms (increased strength of the PFM (p<0.01)). The leakage volume in the 1-h pad test did not decrease in either group. The number of incontinence episodes decreased in the KE group (p<0.05). It also decreased in the KE + BF group, but the difference was not statistically significant (p=0.054). 78.2% of the women in the KE group and 69.6% of the women in the KE + BF group reported an improvement in incontinence (7).

A similar pattern and variables were explored by Ibrahim (2015) and Ong (2015), but they proved a statistically significant difference between the two groups of respondents (22, 23).

Ibrahim et al. investigated the efficacy of BF-assisted Kegel exercises in females with pelvic floor dysfunction in clinical environment in contrast with women who performed Kegel exercises independently at home. Females with neurological conditions, gynaecological or genitourinary surgery and postpartum incontinence were excluded. They proved a statistically significant difference between the investigated groups, and described that biofeedback-assisted Kegel exercises were an effective therapy compared to Kegel exercises alone. As a reason, they mentioned that BF affects the reduction of symptoms in a shorter period and allows exercising of the PFM.
more properly. As many as 19 (79.2%) participants of KE + BF reported improvement of symptoms after 9.7 weeks, compared to 7 participants (31.8%) who reported improvement after 11.8 weeks in KE group. Improved ability to correctly isolate the PFM contraction was reported by 15 participants from the KE + BF group, compared to only 3 participants in the KE group. Greater efficacy of biofeedback in combination with Kegel exercises, when contrasted with Kegel exercises alone, is also demonstrated by manometry, which was performed at the end of the research. Significantly greater improvement was thereby shown on part of the KE + BF group (22.3% compared to 6.1%) (22).

Ong et al. (2015) compared the effectiveness of Kegel exercises performed in combination with the new BF device to Kegel exercises alone (18). They proved that BF therapy resulted in significant early improvement of the symptoms of stress incontinence (p=0.035), and that pelvic muscle strength was significantly better (p=0.025) after 4 weeks of training. The subjective rate of improvement was similar in both groups (62.5% for KE: 61.9% for BF group), p=0.742 (23).

Yeung and associates (2016) compared how Kegel exercises + BF affect pelvic floor muscles as opposed to intra-vaginal electrical stimulation (24). Participants from the BF group achieved better results in assessing urinary symptoms, and reported greater satisfaction with life quality. This may be because BF is more comfortable than intra-vaginal stimulation, as reported by the participants. However, in the case of intra-vaginal electrical stimulation, the number of pads used per day decreased from 2.4 to 1.2, in contrast with the reduction from 2.3 to 2.1 in the BF group. The results showed that both methods were equally effective and that they do not differ in a statistically significant manner (24).

Similar results were also obtained by Terlikowski three years earlier in an investigation of the effects of trans-vaginal electrical stimulation with BF between the active and placebo groups. Using the double-blind test, Terlikowski compared the effect of trans-vaginal electrical stimulation + BF between the active and placebo groups. From the active group, 39% of participants objectively showed a reduction in the number of incontinence episodes, while in the placebo group an objective improvement was not achieved. Subjectively, 45.3% of female patients in the active group considered themselves cured, in contrast to 6.9% in the placebo group. Furthermore, 18.7% reported improvement in contrast to 13.8% in the other group. 26.6% of the participants in the active group reported unchanged status versus 48.3% in the placebo group. Worsening of symptoms was reported by 9.4% in the active group versus 31% of the female patients in the other group (10).

Discussion

Considering that conservative methods improve the initial state in a significant percentage and increase satisfaction with the quality of life, they have been recommended as the first option for treatment of urinary incontinence. One of the most widely studied methods is BF therapy, either as a sole treatment or in combination with other treatment methods.

BF is a useful method because it uses visual, auditory, or tactile signals to give feedback and promotes correct contraction and visualization of muscle activity, because many women are unaware of how to contract their muscles.

It has been proven that BF has a positive effect on motivation and that it encourages constant exercise of pelvic muscles (8, 25). Furthermore, women in assisted BF therapy achieve results which are almost double compared to self-conducted Kegel exercises (26). It should be noted that it is very important to perform the exercises correctly because the likelihood that positive results will last for the next 10 years is increased by 66% if Kegel exercises in the initial stage are successfully and positively evaluated (27).

Past research which compared exercises designed for strengthening PFM with or without BF therapy showed different data related to success and effectiveness. While some studies reported significantly greater improvement and a decrease of symptoms of urinary incontinence after BF therapy, others did not note significant differences which would confirm this theory (7, 10, 22-24).

For the past 30 years, many studies have been conducted to prove the efficacy of BF therapy in the treatment of urinary incontinence.
Berghmans conducted the first larger study in the mid-1990s. The author found that BF in combination with Kegel exercises does not significantly improve the symptoms of incontinence when compared to self-performed Kegel exercises (60%-53%) (12) by performing a systematic review of the literature published in the period of 1980-1996 and conducting a qualitative meta-analysis. This is contrary to the analysis by De Kruif, Wegan and Weatherall who determined that combined BF therapy is more efficient than individual Kegel exercises (28, 29). De Kruif et al. searched MEDLINE and Excerpta Medica and then compared six studies which described PME alone to PME combined with BF. Of these 6 studies, 2 reported statistically significant differences between groups on any outcome measure. The other studies described better outcomes for the BF groups, but authors considered that results were not statistically valid (28). Weatherall performed a quantitative meta-analysis based on the systematic review by Berghmans et al., Burns et al. and Glavind et al. using the number of cured patients as an outcome. Data identified in a previous systematic review were subjected to pooled analysis of odds ratios for the size and variability of each trial. Weatherall identified different conclusions from those in the systematic review mainly due to insufficient power to detect differences in the individual trials, a limitation partially ameliorated by quantitative meta-analysis (29).

Barbosa with her associates (2011) conducted a systematic review of literature and analysed Berghmans’s and two more studies and reached the same conclusion: Kegel exercises are equally effective with or without BF (30).

Pages et al. (2001) compared and analysed individual BF training with group psychological therapy program on the sample of forty women with SUI for 12 weeks. Both therapies were shown to be equally effective in reducing nocturia, but BF therapy resulted in a better subjective outcome (62%) as opposed to the psychological therapy group (28%) (31).

Fitz et al. (2012) proved that Kegel exercises in combination with BF improve pelvic floor muscle function, reduce urinary symptoms and improve the quality of life (32), while Yoo (2011) evaluated the efficacy of BF therapy combined with Kegel exercises for urinary incontinence three months after the completion of treatment (33). Successful therapy meant that no additional treatment was needed, but if a surgical procedure was required after BF therapy, the treatment was evaluated negatively. The study employed a retrospective analysis of the clinical data of 86 women. Treatment was successful for 57% of women who required no further therapy by other methods (33).

Different, non-standardized BF devices, different outcome measures, different measurement methods and indicators of the strength of particular muscle groups, different methods of education and conducting Kegel exercises (individually, in a group, at home or in clinical environment), and different periods of follow-up are just some of the deficiencies and uneveness in results of the same method and different authors.

BF therapy is less time-consuming and more private, but it is more invasive and costly, which is the reason why women disliked this method. The second reason is the use of a vaginal device which is unpleasant for many women (34-36). A non-vaginal device, such as transabdominal ultrasound, may be required in the future (37) because some authors reported pain while training because of the use of tampons or diaphragms, especially in middle-aged and elderly women who were not accustomed to using tampons and diaphragms (34, 36).

In future similar research, the focus should be on BF standardization, in a more homogeneous group because it is difficult to determine the relative effectiveness of BF and Kegel exercises on different outcome measures. Further studies with larger samples designed to consider frequency and duration of follow-up, as well as adherence, are necessary.

Conclusion

The findings of this systematic review have demonstrated that correctly taught BF combined with Kegel exercises and electrical stimulation are an effective treatment for the majority of patients with SUI. The evidence has demonstrated that the combination of BF and Kegel exercises is the best non-surgical treatment for SUI. Out of a total of 5 analysed articles, 4 of them showed that BF, as an additional method, has a positive effect on the increase of pelvic floor
muscle strength and thus on the reduction of involuntarily urination. Only one study suggested that no additive effect of BF training was found and that there were no differences in the outcome between the PFM training with or without BF, and the authors thought that BF was not necessary as a standard add-on treatment.

BF is useful as an adjunct for strengthening PFM, as well as its volume and function. The use of sophisticated equipment such as various BF devices achieves significantly better results in a shorter period of time and is proven to affect the patient’s motivation.

References


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DJELOTVORNOST BIOLOŠKE POVRATNE SPREGE (BIOFEEDBACKA) KAO KONZERVATIVNE METODE LIJEČENJA STRESNE URINARNE INKONTINENCije KOD ŽENA

Sažetak

Cilj je ovog rada sustavnim pregledom literature utvrditi svrhu i djelotvornost primjene biološke povratne sprege (engl. *biofeedback*) kod liječenja stresne inkontinencije.

**Materijali i metode.** Pretraživanjem baze podataka MEDLINE pronađeni su članci povezani s metodom liječenja inkontinencije *biofeedbackom*. Ključne riječi prema kojima se pretraživala baza bile su: „*biofeedback*”, „žene”, „stresna urinarna inkontinencija”. U analizu su bili uključeni samo recenzirani, u cijelosti objavljeni članci, s rezultatima liječenja stresne urinarne inkontinencije (SUI) s pomoću *biofeedbacka* kod žena u dobi od najmanje 18 godina, iz svih dijelova svijeta, bez obzira na to u kojem se okuženju odvijala terapija. Kriteriji uključivanja bili su izvorna istraživanja ne starija od pet godina i pisana na engleskom jeziku.


**Zaključak.** Iako gotovo sve studije (četiri od pet analiziranih) izjavljuju o pozitivnom utjecaju terapije *biofeedbackom* u liječenju stresne inkontinencije, potrebna su daljnja istraživanja na homogenijoj skupini i sa standardiziranim protokolima.

**Ključne riječi:** stresna urinarna inkontinencija, *biofeedback*, žene