Is There Still a Place for Physiotherapy in the Treatment of Female Incontinence?

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Abstract

Objectives: The aim of this article is to report evidence-based knowledge on short- and long-term effects, adverse effects, adherence, dropout and motivational problems of pelvic floor muscle (PFM) training for stress urinary incontinence (SUI).

Methods: Randomised controlled trials (RCTs) retrieved from computerized search, Clinical Practice Guidelines (AHCPR, US), the Cochrane library, and International Consultation on Incontinence (ICI) consensus statements were used as sources of evidence.

Results: Several RCTs have demonstrated that PFM training is more effective than no treatment for SUI. Subjective cure/improvement rates of PFM training reported in RCTs vary between 56 and 70%. Cure rates defined as <2 grams of leakage on different pad tests vary between 44 and 69%. Only one study has analysed data of long-term follow-up for as long as 10 years. Successful results were maintained in two thirds of the patients originally classified as successful.

Conclusions: Pelvic floor muscle training has proved to be an effective treatment for female SUI in RCTs. It has no side effects, and is cost effective compared to surgery. There is a need for more physiotherapists specializing in this area, and better collaboration between urologists and physiotherapists to organize better health services for SUI patients and for planning of future high quality clinical trials.

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1. Introduction

In 1948 Kegel [1] was the first to report pelvic floor muscle (PFM) exercises to be effective in treatment of female urinary incontinence. In spite of his reports of cure rates of >84%, surgery soon became the first choice of treatment, and not until the 1980s was there renewed interest for conservative treatment. This new interest for conservative treatment may have developed because of higher awareness among women on incontinence and health and fitness activities, cost of surgery, and morbidity, complications, and relapses reported after surgical procedures.

However, with the development of minimally invasive surgery procedures such as the Transvaginal Tape (TVT), surgery again seems to be viewed as a quick fix with few adverse effects. Although several consensus statements based on systematic reviews have recommended conservative treatment and especially PFM training as the first choice of treatment for SUI [2,3], many physicians seem to regard the TVT a better first line option than PFM training. The scepticism against PFM training may be based on inappropriate knowledge of exercise science and physiotherapy, beliefs that there is insufficient evidence for the effect of PFM training, that evidence for long-term effect is lacking or poor, and that women are not motivated to regularly perform PFM training. The aim of this paper is to report evidence-based knowledge on the above-mentioned points related to PFM training for SUI.

2. Methods

This review is limited to the effect of physiotherapy on patients with a history of urodynamic SUI. Only
outcome from randomised controlled trials (RCTs) are included. Computerized Search on the Pub Med, studies, data, and conclusions from Clinical Practice Guideline (AHCPR, USA) [2], 2nd International Consultation on Incontinence (ICI) [3], and Cochrane Library of systematic reviews [4,5] have been used as background sources. Physiotherapy techniques to treat SUI include PFM training with or without biofeedback, electrical stimulation and cones [3].

2.1. Is PFM training effective?

The gold standard research design to evaluate the effect of an intervention (surgery, pharmaceutical, training) is RCT. However, there are high and low quality RCTs. High methodology quality is judged on concealment of treatment allocation, blinding of assessors, sufficient sample size (based on power calculation if possible), use of reproducible and valid outcome measurements, and handling of dropouts and low adherence (intention to treat analysis).

Equally important, but less written about in statistical and research textbooks, is the quality of the intervention (good or bad surgery, theory-based and high-quality conducted PFM training). A lot of ineffective or even harmful treatments can be put into a RCT of high methodology quality. These research challenges are the same when conducting RCTs in surgery and PFM training, and the quality of studies of both surgery and PFM training has been judged to be varied [4,6]. For PFM training studies there is an additional problem. Several research groups have shown that >30% of women are not able to voluntary contract the PFM at their first consultation even after thorough individual instruction [7–10]. Hay-Smith et al. [4] reported that only in 15 of 43 RCTs on the effect of PFM training for SUI, urge and mixed incontinence, ability to contract was checked before training started. A common mistake is to strain instead of squeeze and lift. If women are training instead of performing a correct contraction, the training may harm and not improve PFM function.

The numerous reports by Kegel with >80% cure rate comprised uncontrolled studies with the inclusion of a variety of incontinence types and no measurement of urinary leakage before and after treatment. However, since then, several RCTs have demonstrated that PFM exercise is more effective than no treatment to treat SUI [11,12,14–16]. In addition, a number of RCTs have compared PFM training alone with either the use of vaginal resistance devices, biofeedback or vaginal cones [4]. Out of 43 RCTs, only one did not show any significant effect of PFM training on urinary leakage [4]. Interestingly, in this study there was no check of the women's ability to contract, adherence to the training protocol was poor and the placebo group contracted gluteal muscles and external rotators of the hips; activities that may give co-contractions of the PFM [17,18].

2.2. Combined improvement and cure rates

As for surgery [6] and pharmacology studies [19], a combination of cure and improvement measures is often reported. To date there is no consensus on what outcome measure to choose as the gold standard for cure (urodynamic diagnosis, no leakage episodes, ≤2 grams of leakage on pad test (tests with standardized bladder volume, 1 hour, 24 hour, and 48 hour?), women's report, etc) [20]. Subjective cure/improvement rates of PFM training reported in RCTs vary between 56 and 70% [3,4].

2.3. Cure rates

It is often reported that PFM training is more commonly associated with improvement of symptoms, rather than a total cure. However, in several RCTs cure has been reported. In a study by Bo et al. [21] cure rate was defined as conversion of negative to positive closure pressure during cough, and a cure rate of 60% was found. This corresponded with the number of women reporting to be continent or almost continent. In newer RCTs short-term cure rates of 44–69% defined as ≤2 grams of leakage on different pad tests has been found after PFM training [11,14,15,22–24]. The highest cure rate was shown in a single blind RCT where women had thorough individual instruction by a trained PT, combined training with biofeedback, and had close follow-up once and every second week. The training period lasted 6 months. Adherence was high, and dropout was low [24].

2.4. The most effective program

Because of use of different outcome measures and instruments to measure PFM function and strength, it is impossible to combine results between studies, and it is difficult to conclude which training regimen is the more effective. Also the exercise dosage (type of exercise, frequency, duration and intensity) varies significantly between studies [4].

Bo et al. [21] and Wilson et al. [25] have shown that instructor followed up training is significantly more effective than home exercise. Bo et al. combined individual assessment and teaching of correct contraction with strength training in groups in a 6-month training program [11,21]. The women were randomised to either an intensive training program consisting of seven individual sessions with a PT, combined
with 45-minute weekly PFM training classes, and three sets of 8–12 contractions per day at home or the same program except the weekly intensive exercise classes. The results showed a much better improvement in both muscle strength and incontinence in the intensive exercise group. Sixty percent reported to be continent/ almost continent in the intensive exercise group compared to 17% in the less intensive group. A significant reduction of urinary leakage, measured by pad test with standardized bladder volume, was only demonstrated in the intensive exercise group.

This study demonstrated that a huge difference in outcome can be expected according to the intensity and follow-up of the training program, and very little effect can be expected after training without close follow-up. It is worth notifying that the significantly less effective group in this study had seven visits with a skilled PT and that adherence to the home training program was high. Nevertheless, the effect was only 17%. There is a dose-response issue in all sorts of training regimens [26]. Hence, one reason for disappointing effects shown in some clinical practices or research studies may be due to insufficient training stimulus and low dosage [27]. If low dosage programs are chosen as one arm in a RCT comparing PFM training with other methods, PFM training is bound to be less effective.

2.5. Training with biofeedback

Biofeedback has been defined as “a group of experimental procedures where an external sensor is used to give an indication on bodily processes, usually with the purpose of changing the measured quality” [28]. Biofeedback equipment has been developed within the area of psychology, mainly for measurement of sweating, heart rate and blood pressure during different forms of stress. Kegel [1] always based his training protocol on thorough instruction of correct contraction using vaginal palpation and clinical observation. He combined PFM training with use of vaginal squeeze pressure measurement as biofeedback during exercise. Today, a variety of biofeedback apparatus are commonly used in clinical practice to assist with PFM training.

In urology or urogynaecology textbooks the term “biofeedback” is often used to classify a method different from PFM training. However, biofeedback is not a treatment by its own. It is an adjunct to training, measuring the response from a single PFM contraction. In the area of PFM training both vaginal and anal surface EMG, and urethral and vaginal squeeze pressure measurements have been utilized in purpose of making the patients more aware of muscle function, and to enhance and motivate patients’ effort during training [4].

Since Kegel first presented his results, several RCTs have shown that PFM training without biofeedback is more effective than no treatment for SUI [4,11–13]. In women with stress or mixed incontinence, all but one of RCTs have failed to show any additional effect of adding biofeedback to the training protocol. In the study of Glavind et al. [22] a positive effect was demonstrated. However, this study was confounded by a difference in training frequency, and the effect might be due to either a double training dosage, or the use of biofeedback, or both. The results support the studies of Bo et al. and Wilson et al. concluding that there is a dose-response issue in PFM training [21,25].

Since PFM training is effective without biofeedback, a large sample size may be needed to show any beneficial effect of adding biofeedback to an effective training protocol. In most of the published studies the sample sizes are small, and type II errors may have been the reason for negative findings [29]. However, in the two largest RCTs published, no additional effect was demonstrated [4,24].

Many women may not like to undress, lock the room and insert a vaginal or rectal device in order to exercise [30]. On the other hand, some women find it motivating to use biofeedback to control and enhance the strength of the contractions when training. Any factor that may stimulate to high adherence and intensive training should be recommended in purpose of enhancing the effect of a training program.

2.6. Cones

Vaginal cones are weights that are put into the vagina above the levator plate [5]. The theory behind the use of cones in strength training is that the PFM are contracted reflexively or voluntarily when the cone is perceived to slip out. The weight of the cone is supposed to give a training stimulus and make the women contract harder with progressive weight. It has been concluded that training with vaginal cones is more effective than no treatment [5,29]. Five RCTs have been found comparing PFM training with and without vaginal cones for SUI [11,31–34]. Bø et al. [11] found that PFM training was significantly more effective than training with cones both to improve muscle strength and reduce urinary leakage. In the four other studies there were no difference between PFM training with and without cones [32,33]. Cammu and Van Nylen [33] reported very low compliance and therefore did not recommend use of cones. Also in the study of Bø et al. [11] women in the cones group had great motivational problems. Laycock et al. [34] had a total dropout rate in their study of 33%.
The use of cones can be questioned from an exercise science perspective [35]. Holding the cone for as long as 15–20 minutes as recommended might cause decreased blood supply, decreased oxygen consumption, muscle fatigue and pain, and recruit contraction of other muscles instead of the PFM. In addition, many women report that they dislike using cones [33]. On the other hand, the cones may add benefit to the training protocol if used in a different way: the subjects can be asked to contract around the cone and simultaneously try to pull it out in lying or standing position, repeating this 8–12 times in three series per day. In this way, general strength training principles are followed, and progression can be added to the training protocol. Arvonen et al. [36] used “vaginal balls” and followed general strength training principles. They found that training with the balls was significantly more effective in reducing urinary leakage than regular PFM training.

2.7. Electrical stimulation

The aim of electrical stimulation for SUI is to strengthen the PFM mirroring voluntary contractions. Several consensus reports have concluded that strength training is more effective than electrical stimulation to increase muscle strength for other skeletal muscles [37,38]. In most physiotherapy practices, electrical stimulation has been used for partial paralysed muscles and to stimulate to activity when the patients are not able to contract. As soon as the patient can contract voluntarily, most PTs would stop using electrical stimulation and continue with regular muscle training. Surprisingly, in the area of PFM rehabilitation, there has been a great interest especially among gynaecologists and general practitioners to treat urinary incontinence with electrical stimulation. In one of the first studies in this area, Eriksen et al. [39] used long-term stimulation (8 hours a day, usually during sleep, with 10 Hz) and showed significant improvement in urodynamic parameters and urinary leakage. However, the study design was uncontrolled and un-blinded.

Today there are several RCTs on the effect of electrical stimulation on female SUI [29]. A number of different currents, apparatus, and stimulation regimens have been used. For SUI, short-term stimulation applying 35–50 Hz has been used in most of the studies. Electrical stimulation was compared with sham or untreated control in 6 studies for SUI. Henalla et al. [15], Sand et al. [40] and Yamanishi et al. [41] found a significant effect compared to control or sham stimulation, while Lubber and Wolde Tsadik [42], Brubaker et al. [43] and Bø et al. [11] did not find significant effect. It has been concluded that more studies are needed to elucidate if electrical stimulation is effective in treatment of female SUI.

2.8. PFM training or electrical stimulation?

Hennalla et al. [15], Hofbauer et al. [13] and Bø et al. [11] found that PFM training was significantly better than electrical stimulation to treat SUI. Laycock and Jerwood [44] and Hahn et al. [45] found no difference, and Smith [46] found that electrical stimulation was significantly better. Knight et al. [47] and Hofbauer et al. [13] found no effect of adding electrical stimulation to PFM training. Many of these studies are flawed with small numbers, and future RCTs with better methodological quality should be repeated [29]. However, electrical stimulation has shown to have side effects [40], and to be less tolerable to women than PFM training [11]. In addition, Bø and Talseth [48] found that voluntary PFM contraction increases urethral pressure significantly more than electrical stimulation.

2.9. Adverse effects of physiotherapy

Few, if any, adverse effects have been found after PFM exercise [29]. The only reported adverse effect is from Lagro-Jansson [49] where one woman reported pain with exercise and three had an uncomfortable feeling during the exercises. In other studies no side effects have been found [11].

Reported adverse effects after electrical stimulation have been pain, discomfort, vaginal irritations or infections, urinary tract infections and diarrhoea [11,40,50]. In a Norwegian study on 3100 women who had used electrical stimulation 51% reported one or more side effects [50]. The most common side effects were soreness/local irritation (26%), pain (20%), and psychological distress. Most of the cases were mild. Reported adverse effects on cones have been abdominal pain, vaginities and bleeding [11].

2.10. Two concepts of how PFM training may work

There are two main concepts of explaining how PFM training may work for SUI:

1. Teach women a correct contraction and encourage them to voluntarily contract before increase in intra-abdominal pressure.
2. Strength train the muscles to build a structural support (anatomic location of the muscles, proper attachment, tone, hypertrophy) for the bladder and the urethra. A strong structural support (stiff pelvic floor) may prevent descent of the bladder neck and urethra and close the urethra during abrupt increase in intra-abdominal pressure by an automatic quick and strong PFM contraction.
Pre-contractions before increases in intra-abdominal pressures have been part of PFM training in many physiotherapy practices for years [51]. Miller et al. [16] showed that learning women how to contract and teach them to contract before coughing significantly reduced urinary leakage within a week. However, Bump et al. [10] showed that only 49% of women were able to contract the PFM in a way that effectively closed the urethra. To date, we do not know the amount of strength necessary to close the urethra.

In continent subjects, the PFM contraction is an automatic response without conscious voluntary contraction before activity. In addition, such pre-contractions are only possible before single bouts of physical exertion (for instance, sneezing). Nobody can run or dance over a longer period of time and contract the PFM voluntarily all the time. Therefore the main goal for PFM training is to build the muscles to reach the automatic response level.

In some studies the patients were tested both subjectively and objectively during physical activity, and had no leakage during strenuous tests after the training period [11,21,24]. The effect, therefore, most likely was due to improved automatic muscle function and not only ability to voluntary contract before increase in intra-abdominal pressure.

2.11. Long-term effect of PFM training

Several studies have reported long-term effect of PFM training [4]. However, usually women in the non-treatment or less effective intervention groups have gone on to retrieve treatment after cessation of the study period. Follow-up data are therefore usually reported for either all women or for only the group with best effect. As for surgery [52], there are only few long-term studies including clinical examination [53–55]. KlarSKov et al. assessed only a few of the women originally participating in the study. Lagro-Jansen et al. [54] evaluated 88 out of 110 women with stress, urge or mixed incontinence 5 years after cessation of training, and found that 67% remained satisfied with the condition. Only seven of 110 had been treated with surgery. Moreover, satisfaction was closely related to compliance to training and type of incontinence, with mixed incontinent women being more likely to loose the effect. SUI women had the best long-term effect, but only thirty-nine percent of them were exercising daily or “when needed”.

In a 5-year follow-up, Bø and Talseth [55] found that urinary leakage was significantly increased after cessation of organized training. Three of 23 had been treated with surgery. Two of these women who had not been cured after the initial training, were satisfied with their surgery, and had no leakage on pad test. The third woman had been cured after initial PFM training. However, after one year she stopped training because of personal problems connected to the death of her husband. Her incontinence problems returned and she had surgery 2 years before the 5-year follow-up. She was not satisfied with the outcome after surgery and had visible leakage on cough test and 17 grams of leakage on the pad test. Fifty-six percent of the women had a positive closure pressure during cough and 70% had no visible leakage during cough at five-year follow-up. Seventy percent of the patients were still satisfied with the results and did not want other treatment options.

To date the longest long-term follow-up period after PFM training is 10 years. Cammu et al. [56] sent postal questionnaires and evaluated medical files of 52 women who had participated in an individual course of PFM training for urodynamic SUI. Eighty-seven percent were suitable for analysis. Thirty-three percent had had surgery after 10 years. However, only 8% had undergone surgery in the group originally being successful after training, whereas 62% had undergone surgery in the group initially dissatisfied with training. Successful results were maintained after 10 years in two thirds of the patients originally classified as successful.

The general recommendations for maintaining muscle strength are one set of 8–12 contractions twice a week [57]. The intensity of the contraction seems to be more important than frequency of training. So far, no studies have evaluated how many contractions subjects have to perform to maintain PFM strength after cessation of organized training. In a study of Bø and Talseth [55] PFM strength was maintained 5 years after cessation of organized training with 70% exercising more than once a week. However, number and intensity of exercises varied considerably between successful women [58]. One series of 8–12 contractions could easily be instructed in aerobic dance classes or recommended as part of women’s general strength training programs. On the other hand, we do not know how a voluntary pre-contraction before increase in intra-abdominal pressure will maintain or increase muscle strength. In the study of Cammu et al. [56] the long-term effect of PFM training appeared to be attributed to the pre-contraction before sudden increases in intra-abdominal pressure, and not so much to regular strength training. Muscle strength was not measured in their study.

2.12. Motivation

Some women may find the exercises hard to conduct at a regular basis [59]. However, when analysing
results of RCTs, adherence to the exercise program is generally high, and dropout rate is low [4,29]. In a few studies low adherence and high dropout rates have been reported [34,60]. The PTs’ knowledge of behavioural sciences such as pedagogy and health psychology, and their ability to explain and motivate patients may be a crucial factor to enhance adherence and minimize dropouts from training. In some studies such strategies have been followed, and high adherence has been achieved [59,61]. In other studies specific strategies have not been reported, but a lot of emphasize has been put on creating a positive, enjoyable and supportive training environment. Group training after thorough individual instruction may be a good concept if lead by a skilled and motivating person [11,21]. PFM exercise concepts with 0 dropouts [62] and adherence >90% [11] are possible. In a study of Alewijnse [59] most women followed advice of training 4-6 times a week one year after cessation of the training programme. The following factors predicted adherence with 50%: positive intention to adhere, high short-term adherence levels, positive self-efficacy expectations, and frequent weekly episodes of leakage before and after initial therapy. Patients do not comply with treatment for a wide variety of reasons: long-lasting and time-consuming treatments, requirement of life-style changes, poor client/patient interaction, cultural and health beliefs, poor social support, inconvenience, lack of time, motivational problems and travel time to clinics have been listed [63].

In most countries patients receive physiotherapy on physicians referral only. This means that the motivation of the general practitioner, gynaecologist or urologist for PFM training and conservative treatment is extremely important. If these professions are not updated on the effect of PFM training, do not know any trained PTs in their area, or think PFM training is boring and a big demand, the patients may not even be introduced to the option of training. PFM training can either be put forward as a “boring demanding task you need to do the rest of your life” or it can be introduced as a method that is “easy, at a low cost and with no side effects. It may take less than 10 minutes per day to build up strength if it is conducted correctly (three sets of 8-12 contractions a day), and it takes even less to maintain it”. The number of PTs specializing in Women’s Health and pelvic floor issues varies between countries. In order to recruit more PTs into the area, it may be important to motivate for a mandatory curriculum on pelvic floor dysfunction and treatment at undergraduate education level, add courses on postgraduate level, and stimulate urologists to participate in teaching of PTs.

2.13. Is PFM training effective only for the young and those with minor leakage?

Several researchers have looked into factors affecting outcome of PFM exercise on urinary incontinence [29]. No single factor have shown to predict outcome, and it has been concluded that many factors traditionally supposed to affect outcomes such as age and severity of incontinence may be less crucial than previously thought. Factors that appear to be most associated with positive outcome are thorough teaching of correct contraction, motivation, adherence with the intervention, and intensity of the program [29].


One could wonder how a question like this could arise in year 2003. There has never been more evidence from RCTs to support the use of PFM training as the first line treatment for UI. Forty-three RCTs were included in the Cochrane Library systematic review. To date more than 50 RCTs are published which all but one show effect of PFM training. There are no serious adverse effects, and training is cost effective. Consensus statements recognize PFM training as the first choice of treatment [2,29].

On the other hand, when reviewing the literature on surgery, Black and Downs [52] only found 11 RCTs out of 943 publications on the effect of surgery. They concluded that the methodological quality of 31 prospective studies (including the 11 RCTs) was generally poor, and that the evidence as to the effectiveness of surgery is weak. This is supported by Smith et al. [6] stating that the case selection for surgery is varied and often not well described. Often pre- and post-operative evaluation of urinary leakage is missing, and description of surgical techniques and peri-operative complications are omitted. Long-term results after surgery decrease with time. Despite of this, many reports only include short-term follow-up, thereby overestimating the results. Often improvement and cure rates are reported together, and evaluation of impact of complications after surgery is sparse. If a procedure cures stress but creates retention or urge incontinence the surgery should not be classified as successful.

For sling operations the risk of vaginal erosion was found to vary between 0 and 16% and urethral erosion varied from 0 to 5% in the literature [6]. De novo detrusor instability occurred in 3.7-66% of cases, and procedures requiring sling revision or removal range from 1.8 to 35% [6]. After TVT 3-15% of patients have been found to have symptoms of de novo detrusor instability, and short-term voiding disorder has been
found to be 4.3%. Prolene mesh erosion seems to be rare, but knowledge of long-term tolerability of the mesh is lacking [6].

Surgery may affect the effect of later PFM training negatively, while training has no impact on future surgery. According to Ulmsten, the father of TVT, surgery should never be conducted unless extensive physiotherapy has been tried first (personal communications, IUGA, Rome 2000). In two recent editorials Ostergaard [64] and Wall [65] have warned about the widespread use of new surgical techniques before there are high quality RCTs to show the effect and adverse effects.

3. Conclusion

Randomised controlled trials and systematic reviews have shown that PFM training with or without biofeedback has proved to be effective to treat female SUI. Compared to surgery PFM training has no known side effects, is relatively inexpensive, and women should be motivated to intensively perform PFM exercise as first line treatment. However, more than 30% do not contract correctly at their first consultation, and thorough individual instruction is needed. Manual techniques and electrical stimulation may be used to teach how to contract. Three sets of 8–12 close to maximum contractions every day or every second day are recommended based on general strength training theory.

Most women need motivation and encouragement to perform regular strength training. This can be achieved in individual training sessions or in specifically designed PFM training classes. When sufficient function has been achieved, PFM strength has to be maintained by further training, but with lower frequency. More research is needed to find out how much exercise is needed to improve and maintain optimal PFM function, and whether the effect is attributed to a conscious pre-contraction, the building up of a firm structural support giving automatic co-contractions, or a combination. There is a need for better collaboration between the urologist/gynaecologist and the PT to organise a better health service for SUI patients and for planning of future high quality clinical trials.

References


CME questions

Please visit http://www.uroweb.org/updateseries to answer these CME questions on-line. The CME credits will then be attributed automatically.

1. What is the evidence for short-term effect of PFM training in treatment of female SUI?
   A. 20%;
   B. 44–69%;
   C. 84%.

2. How many women initially being successful after PFM training have shown to maintain the effect 10 years later?
   A. None;
   B. 1/3;
   C. 2/3.

3. How many women are not able to contract the PFM at their first consultation?
   A. 10%;
   B. 50%;
   C. 30%.

4. A correct PFM contraction implies
   A. co-contraction of thigh and gluteal muscles;
   B. squeeze around genital openings;
   C. squeeze and lift of genital openings.