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RESEARCH ARTICLE

Dilemmas in the management of female stress incontinence: the role of pelvic floor muscle training

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Abstract Treatment options for female stress urinary incontinence include pelvic floor muscle training, lifestyle interventions, bladder retraining, pharmacotherapy, anti-incontinence devices and surgery. Several consensus statements recommend pelvic floor muscle training as first line treatment. The aim of this review is to analyse all the currently available data and propose a treatment algorithm for clinical practice. A literature-based critical presentation of all treatment modalities, methods of assessing efficacy and comparison between them using a patient-centered approach was made. Many of the studies are observational, non-randomized with several methodological problems that lead to confusion. Emphasis was made to high quality randomized trials. The proposed treatment algorithm established only on evidence-based data. Management strategy however, must identify patient expectations and involve them in the decision-making more than traditional measures of treatment success.

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Introduction

Female incontinence is a common medical problem. Several epidemiologic studies identify a prevalence range of 10–40% in older women living in the community [1–3]. This wide range can be attributed to the definition of urinary incontinence and the research methodology, particularly the use of several questionnaires. The prevalence of incontinence is even higher in institutionalized patients because residents in institutions tend to be older and more impaired than community residing women. The presence of urinary incontinence increase the risk of subsequent hospitalisation and substantially increases the risk of admission into nursing homes independent of age, gender or the presence of any co-morbid condition [4].

The different types of incontinence are usually identified by the questionnaires or interviews used in the epidemiological studies. Urodynamics are rarely used in such studies. Approximately half of all incontinent women are classified as pure stress incontinent, 29% have mixed incontinence and the rest pure urge incontinence [5, 6]. The prevalence of stress incontinence is also increasing with age [7].

Table 1 Treatment options for female stress incontinence

Physiotherapy
Lifestyle interventions
Bladder retraining
Anti-incontinence devices
Pharmacotherapy
Surgical therapy

Stress urinary incontinence is mainly a women's problem. The prevalence in men is estimated in 1–5% only. Incontinence has multiple implications for the patient. It has been noted to be a major barrier to social interests, entertainment, or physical recreation [8]. Depression and anxiety have been linked with incontinence [9]. Besides the profound negative impact of incontinence in patient's quality of life, it is also a major economic problem [10].

Treatment options for female stress urinary incontinence are presented in Table 1. Physiotherapy and especially pelvic floor muscle (PFM) training are recommended as first line treatment by several consensus statements. Despite this recommendation, treatment for female stress incontinence is generally based on personal beliefs of health care providers. An analysis of the methodological quality of the studies is important in order to apply clinical practice guidelines. The aim of this review is to present critically all the current knowledge in the treatment of female stress urinary incontinence elucidating the role of conservative treatment based on PFM training in the management strategy.

Pelvic floor muscle training

The rationale for PFM training is based on two concepts: (1) improvement of urethral resistance and pelvic visceral support, including urethral support, by increasing the strength of the voluntary PFM and (2) voluntary contraction of the PFM before increase in intra-abdominal pressure [11]. The improvement of pelvic floor support will prevent decent of the bladder neck and urethra and closure of the urethra during abrupt increase in intra-abdominal pressure by PFM contraction. An increase in intra-abdominal pressure results in unconscious activation of PFM. Patients can learn to contract these muscles before activities that increase intra-abdominal pressure (e.g. cough) [12]. However, it is impossible for the patients to contract their PFM for a long time. So the clinical improvement may be due to an automatic response level after the training program [13]. In patients with denervation or muscle detachments, the role of PFM training is limited.

These mechanisms have been considered in several studies. No change in urodynamic parameters was found after treatment in patients with clinical improvement [14]. Only 49% of women were able to contract the PFM in a way that effectively closed the urethra [15]. The amount of strength necessary to close the urethra is unknown. These data show that the exact mechanism of action of PFM is not clear.

Pelvic floor muscle training program

The pelvic floor consists of several muscles that include the anal sphincter, the ischiocavernosus, the bulbospongiosus, the transverse perineal muscle, the striated urogenital sphincter and the levator ani (puborectalis, pubococcygeus and iliococcygeus muscles). The PFM are skeletal muscles consisting of 33% fast fibres and 67% slow fibres [16]. The normal function of these muscles is to squeeze around the vaginal, urethral and anal openings and to lift inwards in a cranial direction. The contraction of these muscles is not visible but PFM are possibly contracted synergistically with abdominal, hip adductor and gluteal muscles [17]. Activation of the local stabilising muscles of the lumbo-pelvic region such as transversus abdominis, psoas and lumbar multifidus, facilitates activation of the PFM [18].

The principles of muscle training are overload, specificity, maintenance and reversibility. *Overload* can be achieved by maximum contractions, lengthening of the holding periods, increase number of repetitions and reduced rest intervals. Strength training for skeletal muscles can be achieved by 8–12 slow velocity maximal contractions, 3–4 series, 3–4 times a week [19]. Increased muscle volume can be achieved by even fewer contractions. Maximal contractions and the duration of the exercise period are the most important factors in increasing and maintaining muscle

strength. At least 15–20 weeks of exercise are recommended because the effects in the first 6–8 weeks are mainly caused by neural adaptation (more effective units and increased frequency of excitation) and muscle hypertrophy continues over months and years [20]. Light contractions involve mainly slow twitch fibers and maximum contractions recruit fast twitch fibers [21]. *Specificity* is very important as many patients contract other muscles together or instead of PFM. At least 30% of patients cannot contract these muscles voluntarily or they may do a valsalva maneuver when asked to contract [15]. Co-contraction of other related muscles (e.g. glutei, hip adductors) should be minimized so that the PFM are targeted and their contraction is not masked by strong contractions of other muscle groups. However, it was suggested that it is not possible to maximally contract the PFM without co-contraction of transversus abdominis [18]. *Maintenance* of the training program on a regular basis is important to improve the length of time and the power of the contraction. *Reversibility* means that the length of time and the power of the contraction decline if the patient follows a reduced exercise program (the former quicker than the latter).

There is no standardised treatment program. The patients are recommended to contract their muscles as long as possible and relax for the same time. Initially, some patients are able to contract for only 1–2 s. They gradually increase the duration of the contraction until they reach 10 s. They perform exercises 2–3 times a day in sets of 10–15 to avoid muscle fatigue. The total recommended exercise time is about 6 months.

Biofeedback is an adjunct to training as it measures the response from a single PFM contraction and helps patients to control and enhance the strength of the contractions. Biofeedback involves the use of monitoring instruments (vaginal or anal probes using pressure or electromyographic sensors with information produced in visual and/or auditory form) to detect and amplify the various internal physiologic events or conditions of which the person is usually unaware [22]. Intravaginal resistance devices (e.g. balloon catheters, perineometers) provide resistance to enhance strength training but may also give simultaneous biofeedback.

Weighted vaginal cones were developed as a method of strengthening and testing the function of the PFM without the inconvenience of other forms of biofeedback [23]. Theoretically, the sensation of cone sliping out of the vagina might provide strong sensory feedback and prompt a PFM contraction reflexively or voluntarily in order to retain the cone. The patient inserts the lighest cone into the vagina for 15–30 min while going out her usual activities. If she can retain the cone, then the heavier cone is used. The total number of cones are 3–9 per set, the lighest cone is usually 20 g and the heaviest is 70–100 g [13, 24]. Another treatment protocol includes the contraction around the cone while the patient tries to pull it out in lying or standing position, repeating this 8–12 times, 3 sets per day. This protocol follows better strength training principles [25].

Electrical stimulation aims at strengthening the PFM mirroring voluntary contractions. Electrical stimulation can be used for partial paralysed muscles or for stimulation of muscle activity when the patients are not able to contract. As soon as the patient can contract voluntarily electrical stimulation can be continued with regular muscle training [26].

Efficacy of pelvic floor muscle training

PFM training is significantly better than no treatment or placebo treatment based on self-reported cure/improvement and leakage episodes in women with stress incontinence. Women in the PFM training groups were 7.25 times more likely to be cured than women in no treatment groups and this increased to 23.04 times for combined cure/improvement. It has been suggested that self-reported cure/improvement was a more common outcome than cure alone. To date there is no consensus on what outcome measure to choose as the gold standard for cure (urodynamic diagnosis, no leakage episodes, <2 g of leakage on pad test, women's report, etc.) [27]. Subjective cure or improvement rates of PFM training reported in randomized clinical trials vary between 44 and 70% [28, 29]. Cure has been defined as <2 g of leakage on pad test. The highest cure rate was presented in a study where women had thorough individual instruction by a trained physiotherapist,

close follow-up once every second week and total training period of 6 months [30]. High adherence and low dropout were recorded.

Training programs differ in type of exercise, frequency, duration and intensity. No program can be successful in a patient who is unable to identify or isolate the PFM properly. In Kegel's series, 30% of women could not contract their muscles appropriately and, in another study, 25% of women did a valsalva maneuver when asked to contract [15]. An instructor-followed-up training is significantly more effective than home exercise [31] as well as the total time and the intensity of the training program. One reason for disappointing effects shown in some clinical practices or research studies may be due to insufficient training stimulus and low dosage.

Another important issue is maintaining of muscle strength in the long-term. The general maintaining recommendations are one set of 8–12 contractions twice a week. Long-term effects of PFM training have been reported in several studies. After 10 years, 33% of the patients had surgery. 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 [29]. In two other studies with 5-year follow-up, 67% of the patients remained satisfied and 70% had no visible leakage during cough respectively [32, 33].

Different types of biofeedback were used in several studies [34, 35]. These include a vaginal probe with EMG electrodes or a vaginal probe sensitive to pressure changes. Visual feedback provided in all studies while two devices provided also auditory feedback too. There are data supporting a positive effect of biofeedback versus PFM training alone. In these studies, it was shown that patients had a more rapid reduction in leakage with biofeedback although there was no significant difference in the long term [35, 36]. Other studies did not find any evidence that adding biofeedback has any beneficial effect to PFM training alone [37, 38]. Today, there is no apparent difference in the effectiveness of PFM training with or without biofeedback. However, biofeedback can be considered in certain cases when it may be a useful adjunct to treatment for the purposes of teaching, motivation or compliance.

Weighted vaginal cones are an effective treatment for the treatment of female stress incontinence when compared with no treatment or control treatment. Self-reported cure or improvement was reported between 60–90%, although other measures such as leakage episodes and pad test did not show significant differences between groups [13, 39]. A comparison of PFM training with vaginal cones in several studies shows no difference although the results were confusing [40]. The addition of vaginal cones to PFM training has no beneficial effect. Vaginal cones are no better than electrical stimulation. Treatment with vaginal cones is accompanied with low compliance of the patients, motivational problems and high drop out rates of 33% [41].

Efficacy of electrical stimulation is difficult to be assessed due to the lack of treatment standardization. Therapeutic protocols include anything from a single episode of maximal stimulation under general anaesthetic for 20 min with vaginal and buttock electrodes, to 10 sessions of interferential therapy at 10–40 Hz with perineal body and symphysis pubis electrodes, to 6 months of low intensity stimulation at 10 Hz using a vaginal electrode [42]. In most studies, a short-term stimulation applying 35–50 Hz has been used. The results are confusing. In some studies, a significant effect of electrical stimulation was found compared to control or placebo treatments [26, 43] while in others, there was no beneficial effect [44, 45]. Combination therapy with PFM training did not find any beneficial effect over PFM training alone [46]. Voluntary pelvic floor contractions increase more significantly than electrical stimulation [47]. In conclusion, there are insufficient data today to confirm the efficacy of electrical stimulation in the treatment of stress urinary incontinence. Furthermore electrical stimulation has side effects and it is less tolerable than PFM training [26].

Lifestyle interventions and bladder retraining

Several lifestyle factors are associated with female stress incontinence (Table 2). Alterations

Table 2 Lifestyle factors associated with stress incon-\ tinence

Obesity
Fluid management
Dietary factors (caffeine, alcohol, sweeteners)
Smoking,
Heavy work or high impact activity
Constipation

in lifestyle are frequently recommended by health care professionals and lay people alike. Obesity is an independent risk factor for the prevalence of urinary incontinence. Massive weight loss significantly decreases incontinence in morbidly obese women. Preliminary evidence suggests that moderate weight loss may also result in decreased incontinence. Chronic constipation can be associated with organ prolapse. Data on other factors report only associations and do not assess the actual effect of applying or deleting the behaviour in question on incontinence [48, 49].

Bladder retraining aims at correcting faulty habit patterns of frequent urination, improving ability to control bladder urgency, prolonging voiding intervals, increasing bladder capacity, reducing incontinent episodes, and building patient confidence in controlling bladder function. Efficacy of bladder retraining for the treatment of stress incontinence has been suggested. However, these studies include also patient groups with mixed and urge incontinence. The role of bladder retraining in female stress incontinence needs further study [50, 51].

Anti-incontinence devices

Vaginal support devices (Table 3) could be included in the treatment options when managing women with stress urinary incontinence, dependent upon the availability of product, patient acceptance, and cost and especially in younger patients who may be contemplating further pregnancies [52–55]. However, long-term results are not available and studies comparing these therapies to other forms of conservative therapy or surgery have not been performed.

Devices that occlude the external meatus were found to be of varying efficacy, with minimal morbidity. Adherence to the peri-meatal area is essential, as all devices are occlusive, achieving the effect by either blocking at the meatus or compressing the distal urethral lumen, as opposed to absorptive [52, 56, 57]. However, the method and degree of adherence is the determining factor for the type and severity of local irritation. Patient selection based on motivation, appropriate anatomy, and manual dexterity, in combination with efficacy and morbidity will determine overall satisfaction.

Intraurethral devices occlude the urethral lumen [58, 59]. Most patients who utilize intraurethral devices report dryness or improvement in the laboratory and on diaries. The major morbidities are discomfort, urinary tract infections and hematuria. The role of intraurethral devices in patients, who do not achieve the desired efficacy with other forms of conservative therapy, and wish to avoid surgery, requires further study.

Pharmacotherapy

The stimulation of α1-adrenergic receptors in the bladder neck and the proximal urethra produces an increase in maximum urethral pressure and maximum urethral closure pressure [60]. Women with stress incontinence have lower resting urethral pressures than age-matched continent women [61]. The most widely used drugs are ephedrine (25–60 mg 3–4 times daily) and phenylpropanolamine (50–100 mg 2–3 times daily) [62]. Cure rates of 0–14% and improvement of 19–60% have been recorded especially in patients with minimal to moderate incontinence [63, 64]. The systematic use of these drugs is no longer recommended due to common adverse events and the possible association of phenylpropanolamine with hemorrhagic stroke [65, 66].

Estrogen supplementation in postmenopausal women has been advocated by several non-randomized clinical trials using different types of estrogen (some with progestational agents), with varying doses and routes of administration [67]. A critical analysis shows that the reported improvement was subjective with no change in the volume of urine lost and no change in

Table 3 Anti-incontinence devices for the treatment of female stress incontinence

Name	Description	Efficacy
Intravaginal devices with support to the bladder neck		
	Tampons, pessaries and diaphragms	40% cure on pad weight
Introl	Removable reusable intra-vaginal silastic ring with with two prongs placed behind the symphysis	65–90% reduction in pad weight; 29–83% dry, 15–50% improved
Conveen (clam type)	Folded polyurethrane device expanding 30% when moistened in the vagina	66% reduction in pad weight; 46% of patients continent; 49% improved
Conveen (tampon)	A newer version of the Conveen designed like a tampon	Same as the clam type but preferred by more patients
Ladycon	Expanding polyvinyl alcohol sponge	No leakage in pads
Devices that block the external meatus		
Miniguard	Triangularly shaped foam device that adheres to the peri-meatal area	25% continent, 50% improved, but 25% had worse incontinence
FemAssist	Hat-shaped silicone device, placed over the urethral meatus, and upon release the meatal mucosa is drawn up into the device and the urethral lumen is occluded.	47% continent, 33% had more than 50% benefit, while 9% had worse leakage
Capsure	A device that creates optimal negative pressure that permits coaptation of the urethral sidewalls and increased urethral resistance	82% continent on pad weight, 91% continent on stress test
Intraurethral devices		
Viva	Disposable plastic device composed of an oval meatal plate, a soft stalk with a removable semirigid guide, and spheres along the stalk	67–94% improvement in leakage
Reliance	Disposable inflated balloon	80% complete dryness, 5% improvement on pad weight
Femsoft	Disposable inflated balloon	Decrease in pad weight

Table 4 Pharmacotherapy for female stress urinary incontinence

Drug	Mechanism of action	Remarks
Ephedrine	Non-selective adrenergic agonist	Minimal efficacy
Phenylpropanolamine	Non-selective adrenergic agonist	Not recommended
Methoxamine	Selective α1-adrenergic agonist	Possibly effective, common side effects
Propranolol	β-adrenergic antagonist	No randomized trial support efficacy
Clenbuterol	β2-adrenergic agonist	Undefined mechanism of action
Imipramine	Tricyclic antidepressant that probably enhance the contractile effects of noradrenaline on urethral smooth muscle	No randomized trial support efficacy
Duloxetine	Noradrenaline and serotonin reuptake inhibitor that increases the neural activity to the external urethral sphincter	Under FDA approval
Estrogen	Increase of α-adrenoceptor sensitivity in urethra	Probably not recommended

maximum urethral pressure [68]. These data show that estrogens do not appear to be an effective treatment for stress urinary incontinence.

Although efficacy of imipramine has been suggested in open studies [69, 70], no randomized clinical trial supports its clinical use. Propranolol, clenbuterol and methoxamine were reported to improve stress incontinence in studies with low level of evidence [71–73].

Duloxetine is a combined noradrenaline and serotonin reuptake inhibitor which increases the neural activity to the external urethral sphincter, and increase bladder capacity through central actions in the spinal cord [74]. Results from double-blind, placebo-controlled studies show that duloxetine (40 mg twice daily) decreases incontinence episode frequency (50% vs. 29% on placebo treatment) with comparable improvements in the more severely incontinent subgroup [75–78]. Quality of life scores (Incontinence Quality of Life questionnaire, I-QOL) were also increased after treatment with duloxetine. The discontinuation rate was higher with duloxetine (24% vs. 5% on placebo) with nausea being the most common reason for discontinuation. Nausea was mild to moderate, not progressive and transient. Improvement was evident in the first 4 weeks of treatment. Duloxetine will be the first approved drug for the treatment of female stress incontinence with proven efficacy in randomized clinical trials (Table 4). Further data on long-term efficacy and safety are expected.

Surgery

Surgical management of female stress incontinence included many type of operations based on different principles with variable efficacy rates (Table 5). The anterior colporraphy is associated with minimal morbidity but it is the least likely operation to be efficacious in the long term [79, 80]. Open colposuspension (Burch) is a highly effective surgical treatment [81]. Although efficacy declines with time, this method sustains a high cure rate in the long term [82]. Laparoscopic

Table 5 Surgical procedures for the treatment of female stress incontinence

Procedure	Short-term results	Long-term results
Anterior colporrhaphy	63% cure at 1 year	37% cure at 5 years
Open colposuspension	70–90% cure at 1 year	70% cure at 10–12 years
Laparoscopic colposuspension	80% cure at 1 year	77% cure at 5 years
Marshall–Marchetti–Kranz	90% cure at 1 year	75% cure at 15 years
Endoscopic needle suspension	50–70% cure at 1 year	20% cure at 10 years
Slings	80% cure at 1 year	80% cure at 15 years
Tension-free vaginal tape (TVT)	80–90% cure at 1 year	85% cure at 5 years
Peri-urethral injection	60–90% cure at 6 months	40–50% cure at 2 years
Artificial urinary sphincter	80% cure	60% cure at 10–15 years

colposuspension has similar efficacy rates with the open procedure [83]. The Marshall–Marchetti–Kranz has also a high efficacy rate that sustains in time [84, 85]. It is less popular than the open colposuspension due to an overall 22% complication rate (2.5% osteitis pubis) [86]. Endoscopic needle suspension has a high cure rate in the short term but declines rapidly in the long term [87, 88]. There is almost no indication today to perform such an operation. Slings with an autologous or synthetic material have high efficacy rates that sustain in time [89]. Synthetic material has a higher complication rate (erosion, sinus formation) [90]. Tension free vaginal tape (TVT) is a new treatment with efficacy rates similar to open colposuspension. Long-term results show sustained efficacy rates [91, 92]. However, more studies are needed to document long-term efficacy. Efficacy rates of injectable bulking agents (PTFE, collagen, fat, Macroplastique, Durasphere) declines with time. Many women consider them an acceptable form of treatment because complications are rarely seen [93–95]. Artificial urinary sphincter has a high cure rate but it is accompanied by a high complication rate and revision procedures [96].

Only a few comparative studies exist in the literature. Outcome measures differ and results are often confusing. However, the open procedures (colposuspension, Marshall–Marchetti–Kranz) and the slings have the highest efficacy rates. TVT has similar cure rates, it is a minimally invasive technique but long-term efficacy has to be proved. Efficacy is not sustained in the long-term after anterior colporraphy, endoscopic needle suspensions and bulking agents. Besides efficacy, complication and hospitalization rates favor the sling and the TVT operations [97].

Assessment of effectiveness of treatments for female stress incontinence

In order to assess efficacy of different treatments for female stress incontinence, it is important to define outcome measures. In most clinical trials, the outcome measures are not comparable and there is no consensus on what is the most appropriate instrument to define efficacy. Efficacy is often expressed by means of cure or improvement based on several parameters. Most of the studies use questionnaires, quantification of leakage episodes and rarely urodynamic parameters as maximum urethral closure pressure. Efficacy is not the only treatment outcome. Complications, costs and bother from the various treatment modalities must be carefully analyzed. The quantification of urine leakage is not directly associated with the impact on patient's quality of life. Over the past decade, several quality of life instruments for pelvic floor dysfunction have been developed and validated. Such instruments have been primarily used to assess the impact of urinary incontinence such as the short and long forms of the Incontinence Impact Questionnaire, the Urogenital Distress Inventory and the Contilife [98, 99]. Newer tools are evolving to evaluate prolapse, colorectal and sexual function such as the Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire in women with pelvic floor dysfunction.

Although there is a growing literature on the treatment of female stress incontinence, many questions about efficacy of different treatment modalities are still unanswered. There is a need for high-quality randomized clinical trials that will share common methodology and endpoints. Quality of life issues are highly important and must be part of any study. Otherwise, the results will remain inconclusive.

Management strategy for female stress incontinence: a patient centered approach

Treatment options for female stress incontinence have been critically analyzed. Evidence-based data clearly suggest that PFM training is a highly efficacious treatment modality that lacks complications and does not preclude any other treatment in the future. This program may have a role in prevention of stress incontinence [100]. Although lifestyle interventions and bladder training can help certain patients, only surgery can offer high cure rates. Anti-incontinence devices have low acceptance rate by the patients and the pharmacotherapy is not effective with the exception of duloxetine that is under clinical

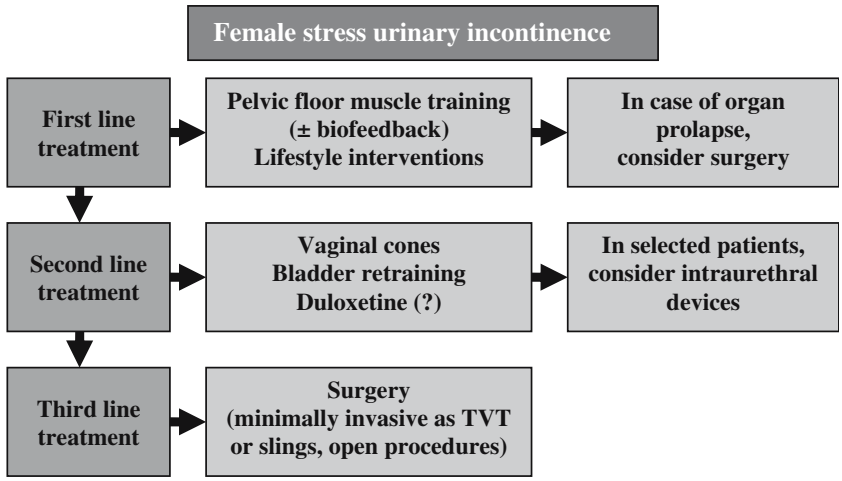

Fig. 1 Treatment algorithm for female stress incontinence

evaluation. However, duloxetine cannot cure stress incontinence. Although there are no data, it could be used in combination with pelvic floor muscle training to obtain quicker clinical results.

Consensus statements consider PFM training with or without biofeedback as the first line treatment for the treatment of female stress incontinence. Despite these statements, many physicians offer surgery as the first line treatment. Surgery in the era of minimally invasive procedures as the Transvaginal Tape (TVT) is made attractive to both physicians and patients because it offers high cure rates in a single session that lasts no more than half an hour and can be done in an outpatient setting. Only, in the presence of organ prolapse, surgery can be offered as first line treatment.

Many physicians believe that the best treatment is the one that offers the highest objective cure rate without significant complications. Objective outcome measures and instruments that measure changes in quality of life have been used for this purpose. However, women with stress incontinence have widely varying expectations consistent with various quality of life disruptions that are personal and highly subjective [101, 102]. Patients most commonly list concerns of symptom relief and maintenance in activities of daily living. Achievement of patient-selected goals is the primary reason for selecting treatment. In treating a disorder that affects quality of life, the patient's perception of her quality of life and goal achievement appears to affect overall satisfaction more than traditional measures of treatment success. Based on these concepts, a treatment algorithm has been proposed (Fig. 1).

Conclusions

PFM training can be a first line treatment for the treatment of female stress incontinence. The motivation of the general practitioner, urologist or gynaecologist for PFM training and conservative treatment is extremely important. In many countries the number of physiotherapists is too low to conduct training programs. In order to recruit more physiotherapists 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 their teaching.

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