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ORIGINAL ARTICLE

Patricia M. Skilling · Peter Petros

Synergistic non-surgical management of pelvic floor dysfunction: second report

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Abstract The normal pelvic floor functions as a balanced synergistic system composed of muscle, connective tissue (CT), and nerve components, with CT being the most vulnerable. The aim was to address a wide range of pelvic floor dysfunctions by strengthening all possible components of the system with minimal time loss, weaving every element of treatment seamlessly into a daily routine. The study group consisted of patients from a tertiary referral pelvic floor clinic who, after testing, opted for nonsurgical treatment of their problem. There were no exclusion criteria. The patients had presented with symptoms which included stress, urge, frequency, nocturia, abnormal emptying and pelvic pain, and the fate of these was tracked prospectively. The regime comprised four visits in 3 months. An anatomical classification guided diagnosis of anatomical defects in the anterior, middle and posterior compartments of the vagina. HRT was administered to all patients, electrotherapy 20 min per day for 4 weeks, squeezing 3×12 per day, reverse pushdowns 3×12 per day and squatting or equivalent up to 20 min per day. Of 147 patients (mean age 52.5 years), 53% completed the programme. Median QOL improvement reported was 66%, mean cough stress test urine loss reduced from 2.2 g (range 0–20.3 g) to 0.2 g (range 0–1.4 g), $p = < 0.005$, and 24-h pad loss from a mean of 3.7 g (range 0–21.8 g) to a mean of 0.76 g (range 0–9.3 m), $p = < 0.005$. Frequency, nocturia and pelvic pain were significantly improved ($p = < 0.005$). Residual urine reduced from mean 202 ml to mean 71 ml ($p = < 0.005$). This method extends indications for nonsurgical therapy beyond stress incontinence, and the results appear to encourage this approach. Confirmation by other investigators is required.

P. M. Skilling (✉) · P. Petros
Kvinno Centre, Suite 14 ASurgicentre,
38 Meadowvale Ave, 6151
South Perth, WA, Australia
E-mail: kvinno@highway1.com.au
Tel.: +61-89-4741966
Fax: +61-89-4743766

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Background

Current pelvic floor rehabilitation (PFR) methods in the female address mainly stress incontinence. Symptoms of instability such as urge, frequency and nocturia are generally treated with anticholinergics and "bladder training", a methodology which trains the inhibitory circuit of the brain. Though it is implicit that pelvic floor rehabilitation exercises cure stress incontinence by strengthening the pelvic floor muscles, how this occurs is rarely mentioned in the literature. There is little place for the pressure equalization theory of Enhorning [1] in this scenario. The other main theories which emphasize the action of the pelvic muscles are those of Shafik [2], who defined a "common sphincter", the puborectalis, and an "individual sphincter" for urethral closure, and De Lancey [3], who stated that the suburethral vagina (hammock) is stabilized by contraction of the anterior portion of pubococcygeus, closure being effected by intraabdominal pressure. Both these theories give a rationale for improvement of stress incontinence symptoms with PFR, but not for symptoms of instability, frequency, nocturia, urgency ('FNU'), abnormal emptying or pelvic pain, symptoms deemed potentially curable, according to the Integral Theory [4], by strengthening the pelvic ligaments, pubourethral (PUL), uterosacral ligaments (USL) and arcus tendineus fasciae pelvis (ATFP).

Though many variations involving various abdominal muscles have been added from time to time, "squeezing", or upward pulling of the pelvic diaphragm, as described by Kegel [5] is the core element of all modern methods.

In 2001 we published our preliminary results using a systems approach to PFR [6] based on the Integral Theory [4]. In essence, this theory postulates that the pelvic floor consists of a closely integrated system whereby three directional muscle forces pull against the pelvic ligaments and fascia to open and close urethra and bladder neck (Fig. 1) and to control urgency (Fig. 2). These structures are co-ordinated by the nervous system, and every component part of the system plays a part: the neuromuscular junction, muscles (fast and slow-twitch), ligaments and connective tissue. It is a fundamental biomechanical concept that strengthening a muscle will also strengthen its insertion point. We hypothesized that strengthening the three directional muscle forces (Fig. 1) would also strengthen PUL, USL, and ATFP. In doing so, we hoped to test the underlying theory [4] for truth or falsity. If it were correct, symptom improvement by non-surgical reinforcement of damaged ligaments should achieve similar results to surgical strengthening thereof [7]. The results from the preliminary study [6] appeared to support that this was so. The aims of the present study were to verify the results of the previous study [6] and to apply more objective criteria to the assessment process.

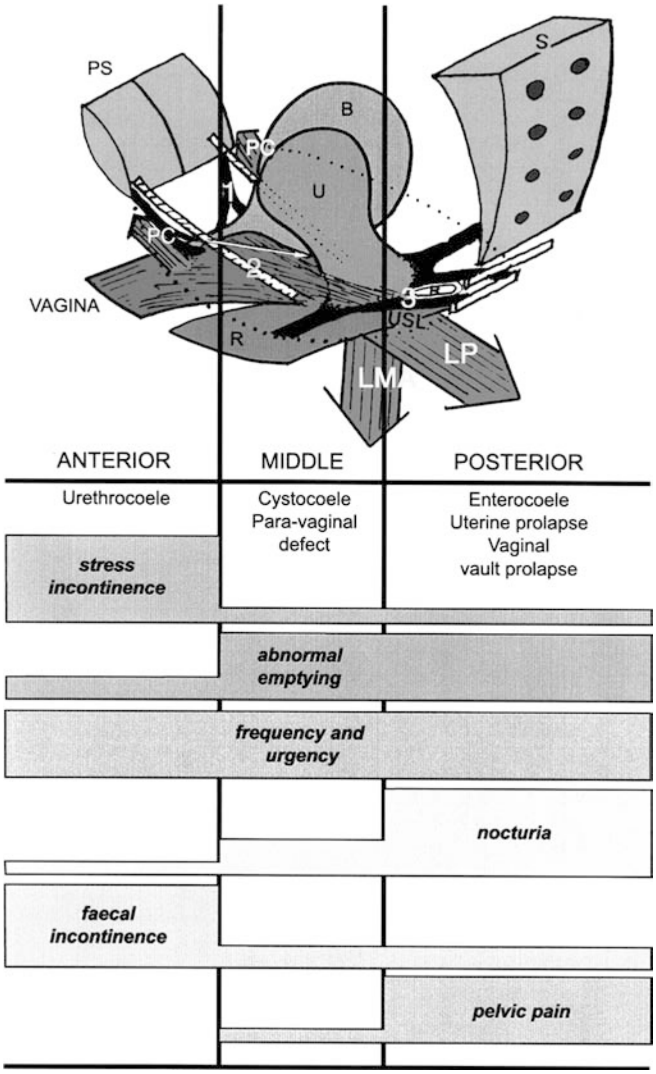

Fig. 1 Diagnostic pictorial algorithm. The vaginal membrane is suspended from the bony pelvis by three ligaments: pubourethral (1), arcus tendineus fascia pelvis (2), and uterosacral (3), which form natural divisions into anterior, posterior and middle zones. The three muscle forces PC (anterior part of pubococcygeus muscle), LP (levator plate) and LMA (longitudinal muscle of the anus) stretch vagina and urethra against the suspensory ligaments to effect closure. Relaxation of the forward force (PC) allows the posterior forces to open the urethra during micturition (*broken lines*). Deficient muscle forces may fail to close urethra (stress incontinence) or open it (abnormal emptying). The algorithm's association with symptoms and anatomical defects is based on previous studies. [4, 7, 11, 18] *S* sacrum,*B* bladder,*U* uterus,*PS* symphysis

Methods

Study group

The study group consisted of 147 patients from a tertiary referral pelvic floor clinic who, after testing, opted for nonsurgical treatment of their problem. The cohort presented variously with symptoms of stress, urge, frequency, nocturia, abnormal emptying and pelvic pain, and the fate of these was tracked prospectively. There were no exclusion criteria. Even patients with large objective loss were included in the cohort if they so chose.

Patient assessment

A rapid cough stress test [8] and 24-h pad test indicated severity of the problem at the 1st visit, and progress at 3 months. Results from

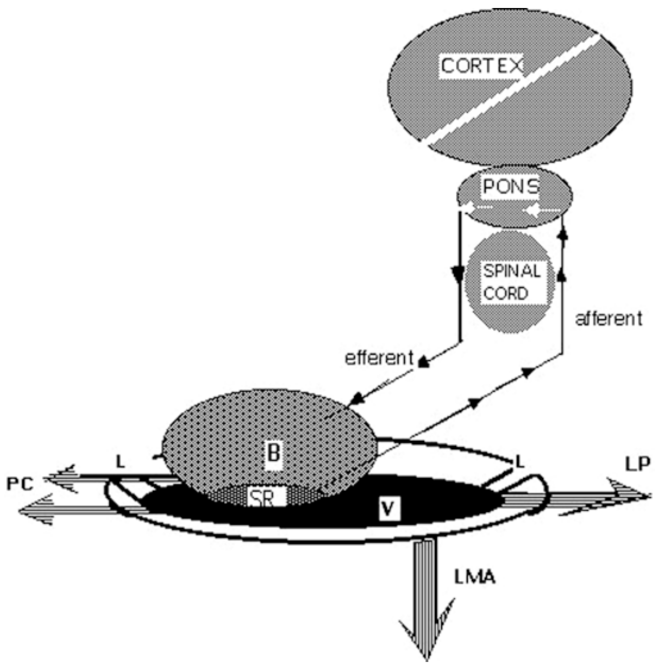

Fig. 2 The trampoline analogy for control of urgency by pelvic floor contraction. The vaginal membrane (*V*) is suspended from the bony pelvis (*trampoline frame*) by ligaments (*L*) (springs). In the normal patient, the hydrostatic pressure of the urine acts on stretch receptors (*SR*) to activate the micturition reflex [4]. If any part of the membrane or any ligament is loose, the muscle forces cannot stretch the vaginal membrane sufficiently to support the urine column. SR fire off at a lower volume and this is perceived by the cortex as frequency, urgency or nocturia.*B* bladder,*LP* levator plate,*PC* anterior portion of pubococcygeus muscle,*LMA* longitudinal muscle of the anus

a semiquantitative questionnaire, examination sheet [4], and dynamic perineal ultrasound comprised the algorithm, which pictorially defined three zones of laxity (Fig. 1). The choice whether to have PFR or when to convert to surgery was always made by the patient, following discussion of the test results with her physician. There were no exclusion criteria.

Rationale for the treatment protocol

As one can never be certain of the contribution of a particular component in pathogenesis, we aimed to strengthen each of these components where possible, the rationale being that even a few percentage points from each component can achieve a significant total improvement. Kegel-type exercises [9] and endovaginal electrotherapy [10] are proven staples of PFR, and they were also in this study. We hypothesize that electrotherapy stimulates the neuromuscular junction, and that "squeezing" stimulates the puborectalis and the forward closure forces (Fig. 1). Prolonged squatting and downward reverse pushdowns were introduced to strengthen the natural slow and fast-twitch components of all three directional muscle closure forces [11] (Fig. 1), the natural movements of closure as proven during radiological studies [4, 11]. This not only strengthens the muscle, it also strengthens its collagenous (ligamentous) insertion points [12]. How these exercises may improve urge, frequency and nocturia is explained by the trampoline analogy (Fig. 2). Good posture was emphasized, as it promotes optimal muscle leverage. All postmenopausal patients were encouraged to take estrogen, systemic or local, to thicken vaginal mucosa and decrease collagen loss [13].

Time efficiency was addressed by limiting attendance at the clinic to a total of four visits in 3 months, by making the pelvic floor methods part of the fabric of a patient's daily routine, and enlisting the patient's participation in planning the treatment.

Treatment protocol

Age, activity, hormonal status and posture were assessed. Some types of HRT oral or vaginal estrogens were prescribed. General exercise and good posture were encouraged. To assist compliance, the patient was required to complete a daily diary.

Electrotherapy

Electrotherapy was introduced at the 1st visit, along with squatting and squeezing exercises. A simple low-cost battery-operated electrical stimulator, the Pelvitoner 2000 (Medhealth Pty Ltd, Perth WA, FAX 61.8.9443 9920), was used for 4 weeks. This delivered a square 50-Hz pulse every 2 s. Positioning of the probe was guided by the pictorial algorithm (Fig. 1). For purely posterior defects (e.g. pelvic pain, high residual urine, nocturia), the probe was inserted into the posterior fornix for 20 min per day. For purely anterior defects (e.g. genuine stress incontinence), the probe was placed just inside the introitus for 20 min every 2nd day, and into the posterior fornix for 20 min every 2nd day. Most patients had mixed incontinence and so the probe was alternated 2nd daily between the front and back of vagina. Bladder suppressant drugs were never used.

Pelvic floor exercises

Squatting and Kegel-type pelvic floor squeezes were introduced at the 1st visit, the latter performed with legs apart according to the methods of Bo [9]. Co-ordination with the electrical stimulator light (biofeedback) was encouraged if possible. At the 2nd visit, a reverse downward thrust was introduced (3 sets of 12 per day) to alternate with squeezing (3 sets of 12 per day). The patient pushed vigorously downwards while pressing upwards with one finger placed on one side of the urethra, approximately 2 cm from the introitus. These exercises aimed to strengthen the tridirectional fast twitch muscle fibres (Fig.1, *arrows*). The "reverse pushdown" exercises were not well tolerated in 2/3 patients, and these patients were told to substitute Kegel exercises.

Squatting was encouraged as a universal slow-twitch exercise, 20 min per day in divided segments, preferably while performing some household task. In patients who could not or would not squat, sitting on a large rubber "fitball" during work or household duties was encouraged. Time management was improved by encouraging patients to perform one group of twelve exercises on waking, retiring, and on visiting the toilet. Also, to substitute squatting for bending at all times. If a patient had arthritis, she was encouraged to sit on the end of a chair or a fitball with legs apart. The 3rd and 4th visits checked patient compliance (diary), discussed how the patient had incorporated the programme into her daily routine, and reinforced the aims and principles of the programme.

Maintenance PFR

By the end of 3 months, it was assumed that the patients had incorporated the exercises into their normal routine. Maintenance electrotherapy was to be performed for 5 days per month. The patient was advised to continue this routine on an ongoing basis. If the patient came to surgery, then it was advised that the PFR be recommenced 12 weeks after surgery.

Results

One hundred and forty-seven patients, mean age 52.5 years (range 25–76) and mean parity 2.25 (range 0–5), commenced the full regime. Ten patients were nulliparous. Surgery included, the dropout rate was 47% (Table 1).

Principal reasons for non-compliance were lack of time, or insufficient motivation. Quality of life (QOL) improvement rate is summarized in Fig. 3 and symptom improvement in Table 2. QOL was a separate question which the patient was asked to answer: *Has your quality of life improved/not improved and by what percentage?* The symptoms improvement was based on the same self-administered questionnaire filled in by the patient prior to her 1st visit.

Improvement rates for individual symptoms are summarized in Table 2. Urine loss for cough stress testing reduced from a mean of 2.2 g (range 0–20.3 g) to 0.2 g (range 0–1.4 g), $p = < 0.005$ (Student's t test), and 24-h pad loss from a mean of 3.7 g (range 0–21.8 g) to a mean of 0.76 g (range 0–9.3 g), $p = < 0.005$ (Fig. 4).

The patients reported that control of urine loss, when achieved, happened even when not "en guarde". The cutoff point for determining frequency improvement was eight times per day and nocturia two times per night. Total number of frequency events for the twelve patients

Table 1 Completion statistics. *Commenced* n = 147, *Completed* n = 78

	1st visit	2nd visit	3rd visit	Total
Dropout rate	25 (17%)	28 (19%)	16 (11%)	69 (47%)

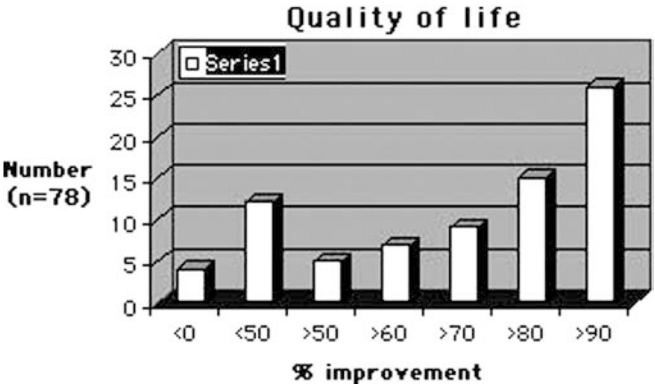

Fig. 3 Quality of life improvement. The *vertical axis* represents actual numbers, and the *horizontal axis* represents % improvement of that particular group. Thus 25 patients improved their QOL by 90%, 11 patients by 50% and so on. On a total symptom basis, the median QOL improvement reported was 66%. In such patients, improvement was evident by the 2nd visit (4 weeks)

Table 2 Fate of individual symptoms*

Symptom	> 50% improvement
Stress incontinence (n = 69)	57 (82%)
Urge incontinence (n = 44)	33 (68%)
Frequency only (n = 12)	10 (83%)
Nocturia (n = 32)	29 (90%)
Pelvic pain (n = 17)	13 (76%)

*Most patients had overlapping symptoms. *n*prevalence of the symptom

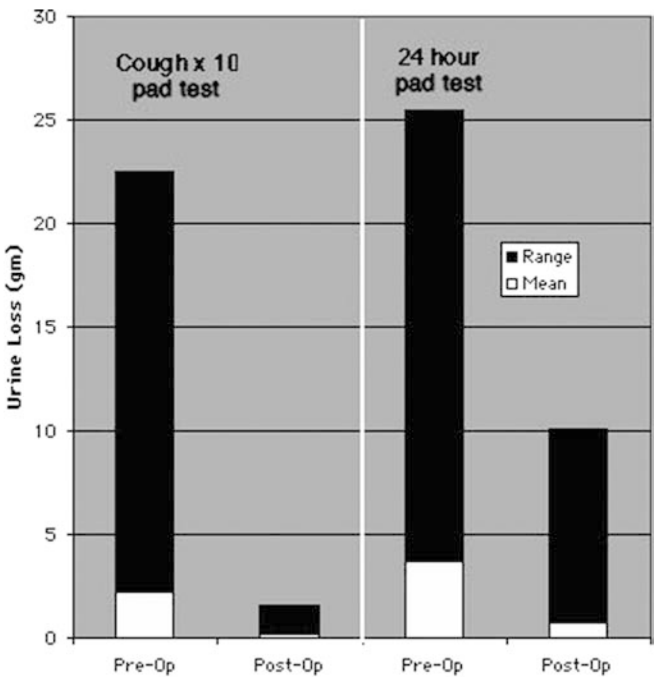

Fig. 4

with only frequency reduced from 140 to 80 per day ($P = < 0.005$). Total number of nocturia events for the 32 patients reduced from 98 events per night to 25 per night ($P = < .005$). In 23 patients with residual urines greater than 50 ml (pre-treatment mean 202 ml, range 50–550 ml), post-treatment residual was reduced to 71 ml (range 15–450 ml) ($p = < 0.005$). Thirteen patients (9% of total) elected to have surgery prior to completion of their course for non-improvement or worsening of stress incontinence. Three patients reported significant worsening of their stress symptoms, and no improvement was noted in nine others. Three patients reported worsening of their urge symptoms, and no improvement was noted in six others. It was not always possible to predict an outcome. The highest cough stress test loss, 20.3 g reduced to 0 g on re-testing. The highest 24-h test loss, 21.8 g reduced to 2.3 g. Yet other patients with far less objective loss required surgery. All patients complied with HRT treatment during the 3-month period.

Discussion

The methods used in this study appear to extend the scope of PFR beyond stress incontinence to urge, frequency, nocturia, abnormal emptying and pelvic pain. This was attributed to the squatting exercise and reverse push-downs, both of which are needed to strengthen the uterosacral ligaments (USL), the key posterior support of the vaginal membrane. According to Petros and Ulmsten [4], damaged USL may cause posterior zone defects, expressed as FNU pelvic pain and abnormal emptying (Fig. 1). On the negative side, worsening of symptoms in six patients (4%) indicates that there must be a threshold beyond which these methods cannot strengthen the pelvic ligaments, and may actually further weaken them.

We attribute the high dropout rate principally to our attitude to treatment, placing responsibility entirely on the patient. Our rationale was that if such a programme was to have any lasting benefit, it needed a disciplined long-term commitment by the patient and a close to zero time impact on her lifestyle. Continuation rate was 52%, inferior to the results from Bo's intensive approach [9], but a median figure compared with other reports which vary between 10 and 80% [14].

Squatting exercises are potentially controversial parts of our management. In deciding to proceed with squatting as an exercise, we were encouraged by Zacharin's findings of thickened collagenous muscle insertions of levator ani in patients who squatted as part of their daily routine [15].

Control of urine loss with the patient "en guarde", a characteristic of the Kegel technique, has been described as "the knack" [16]. We were therefore somewhat surprised to find that those patients reporting cure did NOT leak when caught unawares. We can only explain this finding by postulating that the three directional forces strengthen the pubourethral ligament similarly to reinforcement of that ligament by a plastic tape as per the tension-free vaginal tape operation [17]. The improvement in pelvic pain is attributed to strengthening the uterosacral ligaments, similar to what was achieved surgically [18]. The uterosacral ligaments contain unmyelinated (pain) fibres (PE Petros, unpublished data), and this explains how this type of pelvic pain worsens during the day and is relieved by lying down: the force of gravity pulls on the unsupported nerve causing a ''dragging'' pain.

Popper [19] emphasized the importance of a deductive approach to testing a theory for truth or falsity. The improvement in stress incontinence can be explained by all the three theories described earlier [2, 3, 4]. However, only the Integral Theory can explain the improvement in symptoms of instability (FNU) and abnormal emptying, explained anatomically by strengthening of weakened ligaments (Fig. 2). This takes the theory to a higher (but still not conclusive) level of proof.

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Editorial comment

This study presents an intervention for pelvic floor dysfunction in which the aim was to strengthen all possible components of the system (including pelvic floor muscle, connective tissue and nerves). This approach to the pelvic floor is interesting and apparently effective. The study is hampered by multiple interventions and multiple outcomes, as well as a 50% drop out rate.