

Expert opinion of *EPI-NO Libra* with regard to the therapeutic option as part of conservative incontinence therapy (Pelvic Floor Exercising)

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By *stress urinary incontinence* we mean any involuntary passing of urine during or due to physical strain, which generally leads to an increase of pressure in the abdominal cavity (coughing, sneezing, laughing, climbing stairs etc.). By *urge incontinence* we mean the involuntary loss of urine when there is an irresistible urge to urinate. The loss of urine here typically occurs independently of physical strain. There are often *mixed forms* (mixed stress-urge incontinence).

Urinary incontinence is a common and yet still taboo problem. Estimates assume up to 60% of all women from the age of 40 have to expect this diagnosis. The mental trauma of the women is often severe, but less than half of all women affected seek medical help.

There are many different *causes* of stress urinary incontinence. In the final analysis the disease manifests itself when traumatic, constitutional and / or ageing-related weaknesses of the urethrovesical tissue and its surrounding structures (including the muscles of the pelvic floor) and impairments in the statics of the abdominal and pelvic organs can no longer be compensated. Pregnancy and giving birth are among the most significant risk factors. Depending on the literature, 0.7 – 38% of all mothers report the onset of urinary incontinence after delivery. The persistence rates (5 years after the birth) fluctuate between 25 and 75%.

The *economic significance* of this disease is great. It accounts for 10 – 20% of all major operations carried out in women's clinics (including cystocele and prolapse operations). In 1995, \$26.3 billion was spent in the USA due to urinary incontinence alone. However, spending on incontinence aids (e.g. urinary incontinence

pads) is also increasing. In Germany the costs are already running at around 1 billion Euro (!) per annum. Therefore prophylactic and conservative therapeutic measures are particularly important.

There is a wide *therapeutic range* for urinary incontinence which includes the following concepts: physiotherapeutic and behavioural approaches, changes in lifestyle, pessary therapies, pharmacotherapy and surgical-operative procedures.

Pelvic floor training – in its different forms – is *the* conservative (physio) therapy method used most often. *Indications* are: stress incontinence, urge incontinence and their mixed forms. The aim of pelvic floor training is to strengthen the muscles of the pelvic floor and optimise the co-ordination (the *timing*) of deliberate pelvic floor contractions. The rationale of pelvic floor training for stress urinary incontinence therapy is based on the following observations: (1) Strong and rapid muscles of the pelvic floor are able to constrict the urethra. This increases the intraurethral pressure, meaning that involuntary loss of urine due to an intra-abdominal increase in pressure (possibly by coughing) can be avoided. (2) In addition it was assumed that strong pelvic floor muscles can press the urethra indirectly onto the symphysis pubis, which may further improve urethropraxis. (3) There are also indications that pelvic floor training may improve the co-ordination and the *timing* of the muscle contractions of the pelvic floor. This may avoid the urethra dropping during a sudden increase in pressure in the abdominal cavity. In fact, reflex contractions preceding an intra-abdominal increase in pressure by 200 – 250 milliseconds have been described. Finally, well trained pelvic floor muscles may be more aware of their functions: (1) closing the load-bearing pelvic floor, (2)

preventing the prolapse of the genital organs, urinary and rectal incontinence, (3) affecting posture and co-ordinated movements, (4) affecting urethrovesical and anorectal co-ordinated functions, (5) playing a part in sexuality, in pregnancy and giving birth.

The therapeutic effect of pelvic floor training may be considered proven in the case of stress urinary incontinence. Added to this result is the great meta-analysis of the Cochrane Library: "*Pelvic floor muscle training appeared to be an effective treatment for adult women with stress or mixed incontinence. Pelvic floor muscle training was better than no treatment or placebo treatments.*" Stress incontinence improves in over two thirds of cases. There are also good effects on anal incontinence, sexuality and the quality of life. Experiences in my own patient population prove that (expensive and very risky) operative measures can often be avoided by means of intensive pelvic floor training.

There are usually three stages to pelvic floor training. (1) Awareness of the pelvic floor (after all, over 30% of women cannot tense their pelvic floor). (2) Developing good pelvic floor activity (targeted training of the pelvic floor contraction and muscle development). (3) Integrating what has been learnt into everyday life.

Training aids are useful for the second stage (muscle development). Training aids available include: balls, cones, electrostimulation devices and various biofeedback devices (EMG-based etc.)

For simple self-training, air-filled balloons that are inserted into the vagina and linked to a pressure gauge system (perineometer) are suitable. As long ago as 1948, Arnold Kegel described the successful treatment of 64 women suffering from urinary incontinence with the aid of a perineometer.

The Epi-No device consists of an anatomically adaptable, inflatable silicone balloon (1), a hand pump (2) with a pressure indicator (3) and outlet valve (4) to reduce pressure and a feed tube (5). The device is therefore essentially equivalent to a perineometer and is suitable for pelvic



floor training as part of incontinence therapy on these grounds alone. The elastic balloon that can be inflated at different strengths allows therapy to be individualised to the respective anatomical circumstances (e.g. vaginas are different widths). In addition, the pelvic floor contraction takes place against an (individually adjustable) resistance (balloon). This concept was also described by Kegel in 1948. Finally, through the visualisation of the increase in pressure (pointer on the pressure indicator) a biofeedback signal is displayed, so that the Epi-No device allows a simple form of biofeedback control. Consequently the activity of the pelvic floor muscles can be recognised in the increase in pressure on the balloon. It is important here to ensure through observation and palpation (touching) that the increase in pressure is not triggered by simultaneous activating of the abdominal muscles. This may perhaps be better checked by EMG-based devices. The Epi-No device has two important advantages in comparison with the clearly more expensive EMG-based biofeedback devices: (1) The balloon that is inserted into the vagina is individually adjustable. (2) Training takes place against a resistance. Neither of these is possible with the rigid EMG electrodes.

In summary the following can be ascertained: pelvic floor training with the Epi-No device is based on a therapy concept that has been known for many years (pelvic floor training against resistance with biofeedback). It is known from literature that this form of pelvic floor therapy can be an effective and inexpensive form of therapy for urinary incontinence.

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Munich, 13.01.2003