QRS 1010 Pelvicenter

Repetitive peripheral magnetic stimulation to correct functional pelvic floor disorders

Scientific documentation and medical information

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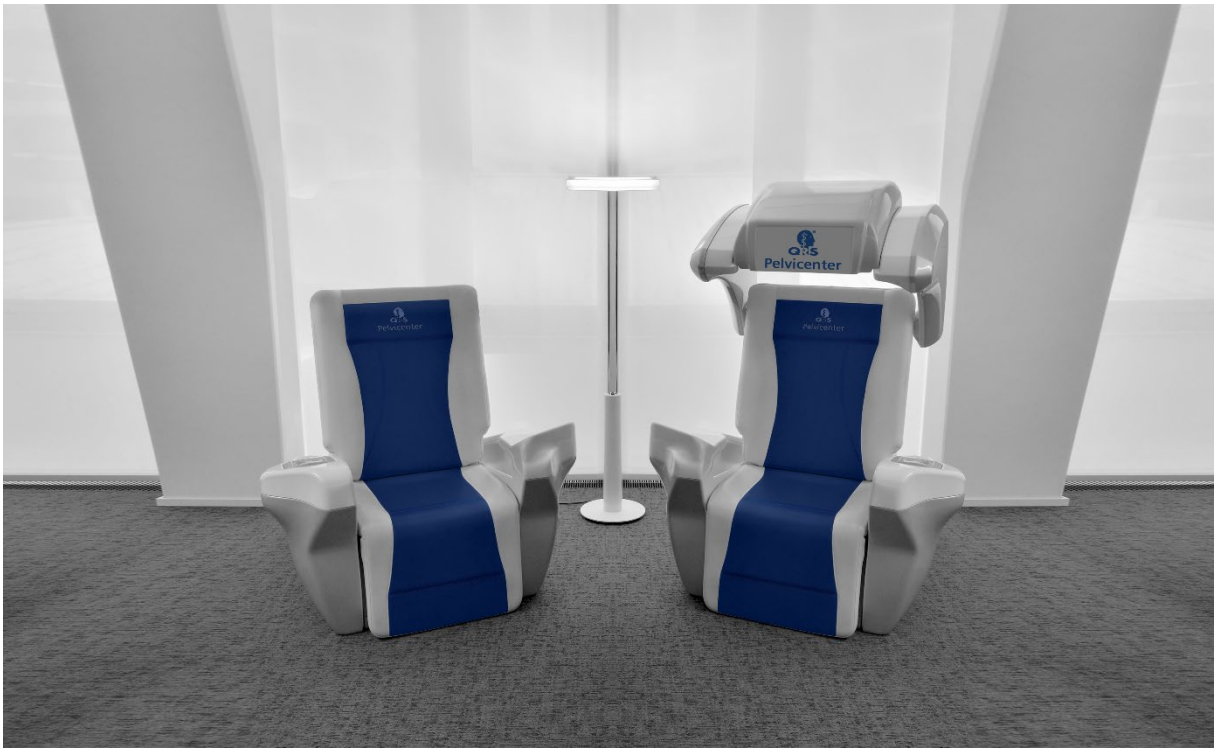
women with stress incontinence



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definition

Stress incontinence (formerly stress incontinence / SUI) describes a condition that is caused by insufficient bladder closure. Sudden pressure increases (e.g. coughing, sneezing, lifting, standing up, jumping, climbing stairs, etc.) can no longer be adequately absorbed with the consequence of an unwanted urine leakage from an insufficient pelvic floor (muscular and connective tissue structures). Pelvic floor insufficiency is a disease that can largely affect all areas of life of an affected person and thus their quality of life - depending on the severity.

Epidemiology and Prevalence

The prevalence data differ considerably between individual authors. We refrain from listing the various evaluations and the various reasons for the deviations. In the following information, we concentrate on prevalence data from the so-called EPINCONT study, which is listed in the brochure of the Robert Koch Institute "Federal Health Reporting" [1] . This study usefully differentiates between different forms of urinary incontinence and also highlights the prevalence of "seriously affected".

Occurrence of urinary incontinence (all forms) in women overall:	
under 30 years	12% (light 57%, moderate 31%, heavy 12%)
between 50 to 54 years	30% (light 46%, medium 33%, heavy 21%)
over 90 years	40% (light 24%, medium 31%, heavy 44%)
Differentiation between the forms of urinary incontinence:	
stress incontinence	**50%**
urge incontinence	11%
mixed incontinence	36%
Other	3%
The prevalence data of the highest severity by age subdivision:	
stress incontinence	**17% (25-44 y. 10% | 45-59 y. 15% | 60+ 33%)**
urge incontinence	28% (25-44 y. 8% | 45-59 y. 18% | 60+ 45%)
mixed incontinence	38% (25-44 y. 19% | 45-59 y. 33% | 60+ 53%)

Table: Prevalence data from the EPINCONT study - Brochure Robert Koch Institute - "Federal Health Reporting"

physiology

The physiology of urination is based on a system of smooth urinary bladder muscles (m. detrusor vesicae), parts of which extend into the urethra. In addition, there is a dependency on the central perception and impulse control, which are located in the representation center for sensory stimuli. Assessing the functionality of a pelvic floor solely by its muscular strength neglects the dependence on central perception and impulse control. This is located in the gyrus pre- and postcentralis of the somatosensory cortex (brain cortex), i.e. the representation center for sensory stimuli (postcentralis) and activities of all muscles of the body periphery (precentralis), including the invisible pelvic floor.

This also makes it easy to see why a vicious circle always begins with a muscular deficit: weakened muscle contractions not only reduce the proprioceptive signals ("muscle spindles") at the spinal reflex arc ("switching of the Ia fiber signals to the A-alpha motoneurons '), but also lead (via the thalamus) to reduced signals to the motor cortex. Which in turn takes this as an opportunity to slowly dissolve the relevant synaptic connections, so that the representation and coordination ability for the motor units of the muscle fibers of the pelvic floor is reduced.

The locking system consists of 3 locking mechanisms:

1. At the transition from the urinary bladder to the urethra, the urinary bladder occlusion No. 1 (M. Sphincter urethrae internus) can be found. When the detrusor contracts for micturition purposes, the sphincter opens, and at the same time the urethra also shortens ("muscle fibers of the detrusor reach into the urethra") [2].
2. The (external) bladder closure No. 2 (M. Sphincter uretrae externus) ensures resting continence. When the intra-abdominal pressure increases, the resulting pressure is transmitted passively-mechanically via the muscular and connective tissue pelvic floor (mainly via the prostate in men) to the urethra in a compressing manner.
3. The additional, third locking mechanism occurs through the reflex contraction of the muscles. When the pressure in the abdomen increases (sneezing, coughing, moving), the bladder is pulled backwards and downwards on the levator plate or the muscles of the anus. At the same time, the pubococcygeus muscle (attached to the pubic bone) pulls the vagina and thus the lower part of the urethra forward and slightly upward. The proximal part of the urethra, which is not fixed, is stretched and bent like an elastic tube.

QRS Pelvicenter rPMS effect

An rPMS-mediated stimulation of the pelvic floor is based on the principles of general strength and endurance training and an improvement in the coordination ability of the trunk area.

Repeated rPMS training, in which the entire musculature of the pelvic floor is addressed, strengthens the circuitry of the motor cortex and demonstrates the neuroplasticity of the CNS [12], [13], [14], [15]. The underlying sensorimotor influx corresponds to the lost physiological proprioceptive afferents during active movements and can replace them, so to speak [16].

rPMS magnetic fields penetrate the organism without resistance and can thus penetrate deep into the tissue. Only the intensity (field strength / flux density), which

is reduced as the square of the distance, is effective. In contrast to electrostimulation, magnetic stimulation is a kind of "refined transport medium" that does not have to channel the electrical current through the tissue with difficulty and resistance, but only allows it to develop inside the organism through the flow of ions. Once at the target site (motor nerves), there is virtually no difference between electrical and magnetic nerve stimulation [3].

The electrical stimulus is transmitted to the muscle via the so-called motor endplate. The axon of the nerve cell branches out until each muscle fiber is reached by a nerve. The stronger the branching, the more individual muscle fibers can be supplied and the more precisely the muscle can be controlled.

A motor nerve fiber innervates, depending on the number of its branches, 3 to 2,000 muscle fibers ("motor unit"), depending on whether the muscle group works with gross or fine motor skills. For example, for the muscles of the finger extensor, one motor unit innervates only 10 to 15 muscle fibers [4], which enables a finer gradation of the motor function, the flexor muscle of the arm (M. biceps brachii) supplies a single motor unit with 750 muscle fibers. The “all or nothing principle” applies to all innervated striated muscle fibers, ie in a motor unit either all innervated striated muscle fibers contract simultaneously or none [5].

The resting potential of peripheral nerve cells is between -65 to -75 mV, with changes of -10 to -20 mV already causing a depolarization of the nerve cell. Therefore, with an electromagnetic induction (rPMS) of high intensity ("needle impulse"), a potential shift is possible at any time, which consequently ends in a depolarization or an action potential.

This primarily affects only the thick, myelinated and therefore fast-conducting nerve fibers (A alpha / Ø 10 to 20 µm / conduction speed 60 to 120 m/s [6] or class I according to the Lloyd/Hunt classification). These mixed sensorimotor nerves contain no pain afferents, so rPMS stimulation is virtually painless [7].

Basically, thin, unmyelinated pain fibers (type C / Ø 0.5 to 1.5 µm / 0.5 to 2m/s) are not activated. For the same reason, the sacral nerve fibers of the parasympathetic (type C) remain unresponsive. Since the stimulus threshold for skeletal muscles is much higher than for nerve cells, direct muscle stimulation is impossible [8].

An rPMS-related polarization lowers the membrane potential of the neighboring neurons, so that the initial impulse jumps like a chain reaction to the motor endplate and the corresponding muscle fibers. The result is a strong muscle contraction depending on the intensity used, the change over time and the frequency. From a frequency of about 20 Hz, a tetanic muscle contraction (continuous contraction) occurs, which could be demonstrated, for example, in an EMG-controlled examination of the lower leg muscles [9].

Training using rPMS results from the repetition of motor impulses. It makes no difference whether the training refers to a concentric or isometric contraction. Since rPMS only generates action potentials on medullary motor nerves (type 1a/b), the medullary afferent fibers of proprioception also react accordingly.

In urinary incontinent women with stress urinary incontinence, the delay between neural stimulus and slow muscle contraction is more pronounced than in continent women [10] . It appears that the innervation of the pelvic floor muscles is damaged. As a result, the associated muscle fibers atrophy (atrophy).

However, nearby unaffected nerve fibers can force reinnervation and even change their morphology from originally fast fibers to slow fibers, thus maintaining the functional integrity of the pelvic floor [11] . Muscles therefore have a considerable potential for self-repair - if a corresponding stimulus is present.

Scope of treatment and duration of therapy

12 therapy sessions with a training duration of 15 minutes each represent the minimum of a treatment series on the QRS Pelvicenter and are recommended for slight urine loss (dribbling up to grade 1). As a rule, a noticeable improvement in symptoms is already evident after 5 to 6 treatments. In the case of higher degrees of severity (grades 2 and 3 / according to Stamey), 16 to 24 therapy units should be scheduled for stress incontinence. The periodic repetition periods of 2 to 3 therapy sessions per week must be taken into account. In a series of 12 treatments, the entire rPMS therapy period extends to 4 to 6 weeks, in a series of 20 to 24 to 8 to 12 weeks.

Effectiveness through maximum strength training and the right frequency

The majority of patients get used to the stimulation effect or the neuromuscular stimulus on the pelvic floor muscles and their surroundings relatively quickly. In rare cases, especially in old age, patients react overly sensitively to the stimulation stimulus. During the first therapy session on the QRS Pelvicenter, the subjective feeling of the patient should therefore be observed and, if necessary, treated with a low intensity level. In principle, in the further course of the therapy series, an attempt should be made to reach high intensities as quickly as possible. Maximum strength is only required at high intensities and the highest possible contraction stimulus on the pelvic floor muscles is thus achieved.

The selection of the correct frequency settings and their chronological sequence is explained in more detail in the QRS Pelvicenter manual. You will receive this as the operator of a QRS Pelvicenter. The instructor will also explain this topic in detail when setting up the device.

Increased effectiveness through self-exercises

The effect of the rPMS therapy can be supported by self-exercises. The healing rate may be increased. However, it should be noted that rPMS training is de facto much more intense and demands significantly more from the muscles than analogous pelvic floor exercises. In order to avoid overload reactions, analog Bebo training should only be carried out in the low-intensity range.

Shortened treatment period

Theoretically, it is also possible to carry out the therapy within a shorter period of time. For example, if the patient is in a spa facility or rehabilitation measure during a 3-week cure. This is practiced in some spa clinics and has not led to any known negative consequences. In such a case, a series of 12 in 3 weeks with 4 treatments per week will be performed. It should be noted that there is a day off between the individual therapy sessions on the QRS Pelvicenter. In order to avoid overuse or muscle soreness, the patient should not do any further pelvic floor exercises or similarly demanding activities or exercises during the therapy period.

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expectation of success

A remission ("__ HYPERLINK "https://pelvicenter.com/wp-admin/post.php?post=121&action=edit" \l "_edn13" dry"), or symptom improvement ("lower pad consumption") can be expected. The success rates of stress incontinence are higher than those of urge and mixed incontinence [14] . In a QRS Pelvicenter study with high evidence (Jadad score 5), for example, the healing rate of stress incontinence ("absolutely dry") after 16 applications is almost 42% [15] .

The therapeutic success persists for an average of 6 to 12 months, although in individual cases it can be 1.1 [16] , 2.2 [17] or even 2.9 years [18] . Representative of this is a study in which, after 6 months of follow-up, 47% were absolutely "dry" and 39% had had their daily episodes of urinary leakage fall from 3.2 to 1.3 [19] . The relatively long-lasting success is probably related to an increased cerebral increase in cortical representation [20] , which means that more muscle fibers of the pelvic floor are addressed if necessary (intra-abdominal "pressure increase"). The natural contractions of the pelvic floor develop their own training effect.

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study situation

To date (July 2018), a total of 72 studies and 5 reviews have been carried out on the effectiveness of rPMS magnetic stimulation of the pelvic floor in stress incontinence.

Below we present the current studies from 2017 and 2018.

Study 1 (2017): randomized, placebo-controlled study with QRS Pelvicenter rPMS [26]

In a current randomized, sham-controlled study, the difficult patient cohort of 39 women (stress incontinence) was examined, in whom active pelvic floor training had previously been unsuccessful. For rPMS treatment, the group was randomized at a ratio of 2:1 to either an active or a sham group, which meant that - after 9 patients had dropped out - 18 active and 12 placebo patients could ultimately be evaluated. The rPMS took place twice a week for 10 weeks, ie a total of 20 sessions were carried out. The primary study endpoint was changes in the number of incontinence episodes/week. Secondary endpoints were the degree of incontinence (g urine/day in the pad test), the total score in the ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form), the ICIQ score for examining quality of life

and abdominal ALPP (leak point pressure), i.e the pressure above which urine leakage occurs.

Result:

The number of episodes/week, the degree of incontinence, the total ICIQ-SF and ICIQ-QOL score as well as ALPP improved significantly ($p<0.05$) compared to baseline in the active group only, while in the sham- group came to no change. There was also a significant intergroup difference in favor of the treatment group with regard to changes from baseline in ICIQ-SF and ALPP ($p < 0.05$). The authors conclude that (urodynamic) stress urinary incontinence can be effectively treated with rPMS.

Study 2 (2017): randomized, double-blind and placebo-controlled study (RCT level 5 according to the Jadad scale) with QRS Pelvicenter rPMS [27]

In the not uncommon proliferation of methodological errors, this randomized, double-blind and placebo-controlled study (QRS Pelvicenter system) occupies a special position, as it is the first study on rPMS to be rated with the highest possible RCT level 5 according to the Jadad scale .

Not every clinical study is optimally planned, conducted and evaluated and is therefore exposed to the risk of systematic errors that can falsify the study results (bias) [28] . The validated Jadad score refers to the methodology of a clinical study or to its randomization, blinding and description of the patient progression [29] . In this case, this was already taken into account in the planning of the study by publishing the study protocol in a separate publication [30] . It is therefore worth taking a closer look at this study:

120 patients (Ø 52 years / 21 - 70 years) whose stress incontinence had existed for at least 1 year (47%), 5 years (20%) or 10 years (23%). 53% had stage 1 and 35% stage 2 prolapse as concomitant disease. The women were randomized into an active (60 people) and a sham group (60 people) and received rPMS twice a week (20 minutes each) for 8 weeks. The sham stimulation was carried out by technically lowering the magnetic coil so that, despite the audible stimulation noise of the pelvic center, it was practically impossible to stimulate motor nerves in the pelvis. Both study groups had no contact with each other. The primary endpoint was any improvement in involuntary urinary leakage (ICIQ-UI SF Score 1-21). Further targets are healing, incontinence-related symptoms (frequency of incontinence episodes, urine leakage in the 1-hour pad test and the muscle strength of the pelvic floor) as well as recording the health-related quality of life (PGI-I). The safety of the rPMS method should also be determined. A follow-up is planned for long-term success after 3 months, 6 months, 12 months and 3 years.

Result:

All 120 patients completed the planned 16 treatments (no drop-out). 57 participants, mainly from the sham group, decided to take another 16 treatments - but on the "real" QRS Pelvicenter.

Primary Outcome:

In the active group, 75% improved at least 5 points according to ICIQ-UI SF (Sham 21.7%), of which 41.7% were completely dry (objective measurement). In the sham group, only 6.7% were completely dry ($p<0.001$). The active group was 3.5 times more likely to improve continence and 6 times more likely to become completely dry compared to placebo. In addition, success improved further with 20 or even 24 treatments. The definition of "dry" was based on the 1-hour pad test.

Secondary Outcome:

The average number of incontinence episodes decreased from 1.77 to 0.46 (Sham: increase from 1.44 to 1.57), decrease in urine loss (pad weight) in the 1-hour pad test from 11.00 g to 3 .02 g (Sham: 11.57 g to 9.77 g) ($p<0.006$) urine leakage situations per day. Pad weight decreased by ≥ 50% in 81.7% of active group participants. Here, too, the success rate improved after another 4 or 8 treatments on the QRS Pelvicenter.

With regard to the degree of incontinence, defined using the ICIQ-UI SF scoring in “mild” (1 to 5 points), “moderate” (6 to 12 points), “severe” (13 to 18 points) and “very severe” (19th to 21 points), 81.7% of QRS Pelvicenter users (Sham 36.7%) reached the next lower level ($p < 0.001$). 11 of 14 patients improved from "severe" to a lower category and 41 of 60 patients improved from "moderate or severe" to "mild" or no symptoms. The results did not strictly correlate with pelvic floor muscle strength. Although a significant improvement in muscle strength was achieved, it did not reach statistical significance compared to placebo.

The reason for this could be found in the test used here ("Urodynamic Bladder Pressure Test"), which measures the entirety of all coordinative muscles of the pelvic floor instead of the strength of individual local muscles near the vagina. Which also makes sense, since the entire muscle accomplishes the continence. Due to the high statistical deviations of the individual measurement results, however, the study was underpowered in terms of its sample size.

Overall, the treatment is 100% safe. 5.3% of the patients in the active group and 8.6% in the sham group reported minor side effects. This means that no relevant undesirable effects can be assumed for rPMS.

Study 3 (2018): Analysis of perception and satisfaction according to the Likert scale with QRS Pelvicenter rPMS

After 65% of the QRS Pelvicenter patients in the PGI-I in a QRS Pelvicenter study had judged a significant improvement (Sham 18.3%) ($p < 0.001$) in terms of perception and satisfaction with rPMS treatment, this aspect was considered analyzed in more detail in a separate study [31] . The participants had to answer seven questions (5-point Likert scale). Questions related to (1) discomfort with treatment, (2) pain, (3) anxiety, (4) convenience in coming for treatment, (5) level of motivation to continue treatment, (6) likelihood of receiving additional rPMS (7) Likelihood of recommending rPMS therapy to friends with SUI symptoms. For this purpose, the

Likert scale developed by the American psychologist Rensis Likert was used, which has proven itself for measuring personal attitudes [32] . The response scale weighted according to five characteristics: a score of 1 or 2 is evaluated as negative, 3 as neutral and a score of 4 or 5 as positive.

Result:

After 2 months, 80.7% of the patients in the intervention group stated that they found the treatment pleasant. The treatment was not painful for 82.5%, and 89.5% were not afraid. Accessing treatment was also not difficult for 78.9%, 77.2% were motivated to continue treatment, 78.9% wanted to seek additional treatment if necessary and 89.5% gave to recommend the rPMS with the QRS Pelvicenter to friends with SUI. There was no difference between the two groups (active or sham) ($p<0.05$).

With regard to satisfaction with rPMS, this was confirmed in the active group with 82.4% and in the sham group with 46.6% ($p < 0.001$). Correlatively, a significantly higher proportion in the active group (68.4%) felt either much or very much better than in the placebo group at 19.0% ($p<0.001$).

Side effects:

5.3% of patients in the active group and 8.6% in the sham group reported minor side effects that did not require treatment. In the active treatment group, they consisted of pain in the gluteal muscles and hip bones, burning sensation when urinating, or a yellow vaginal discharge without evidence of infection. The side effects in the placebo group were constipation, delayed menstruation, mouth ulcers, difficulty urinating and diarrhea. Treatment acceptance was high and there were no discontinuations. There were no significant group differences in uroflowmetry (urine flow measurement).

In summary and compared to other studies from USA [33] , [34] , Japan [35] , [36] , [37] , Korea [38] and Turkey [39] , [40] the side effects are so minor that the rPMS can be described as a well tolerated and painless procedure.

Study 4 (2018): IDEAL-D-2b study, review of quality of life (QoL) after 1 year of treatment with QRS Pelvicenter rPMS

In the continuation of the study mentioned (120 women with stress incontinence / use of the QRS Pelvicenter system), the patients could choose after 16 treatments (2 months) whether they wanted to receive an additional 16 treatments - regardless of the initial randomization. The primary response criterion was a 7-point reduction in ICIQ-LUTSqol (Incontinence Questionaire-Lower Urinary Tract Symptoms Quality of Life). A follow-up was planned after 1, 2, 5, 8 and 14 months.

The background and main motivation for this additional investigation was a systematic review (already cited) [41] , in which it turned out that of the 3 RCT studies that examined the effectiveness of rPMS in SUI, either did not relate to quality of life [42] , or only related to mixed-composite measurements [43] , [44] . In addition, these studies had small sample sizes and only had a short follow-up period.

Also, no study is known in which the influence of rPMS on the different aspects of the quality of life (QoL) of SUI patients was examined. It therefore seems necessary to conduct this on the basis of an IDEAL-D-2b study.

IDEAL-D framework (**Innovation** , **D evelopment** , Exploration, Assessment and Long **-** term - **Devices**) [45] is **a** new instrument for improving study quality, which primarily focuses on the transparency of the data collected and a strict reporting relates. There are a number of recommendations for this, which are designated phase 1 (idea), 2a (development), 2b (exploration), 3 (assessment) and 4 (long-term study), depending on the area examined [46] . For example, 2b (exploration) requires, among other things, a more disease-related than process-related investigation and a validation of the method, for example according to CUSUM (**cumulative** sum **charts**).

Result QoL after 8 weeks:

Using the smallest clinically relevant difference (MCID) of a 7-point reduction, at 8 weeks, 58% of the active group and 21% of the sham group were therapy responders (p<0.006). The mean difference in the mean standard error of the ICIQ-LUTSqol total score (in %) was -8.74 +/- 1.25 in the active group versus 4.10 +/- 1.08 in the sham group. The mean efficacy score was -2.63 +/- 0.32 versus -1.19 +/- 0.30. Household chores, job, physical activity, travel, pad use, social life, relationships, sexuality, family, depression, anxiety / nervousness, poor self-reflection, sleep, fatigue, fluid restriction, clothing issues, smell and impairments were examined. When asked to improve by at least one grade, significantly more women responded than to Sham for physical activity, travel, depression, pad use, clothing issues, smelling, and other impairments. Physical activity improved the most here (63.3% versus sham 36.7%) (p < 0.002).

Result after 14 months (1 year after treatment):

At 1 year, more patients were QOL responders (67%) regardless of whether they had received 16 or 32 applications compared to those not treated with rPMS at all (25% / p<0.001). The influence on physical activity was strongest.

Study 5 (2017): Follow-up of the QRS Pelvicenter study RCT level 5 at 14 months

This study relates to the follow-up of the QRS Pelvicenter study (Lim et al. 2015) conducted 14 months later. By then, 120 participants had received either active rPMS or placebo treatment for 8 weeks (16 applications), and 24 women in the intervention group and 41 in the placebo group had received a further 16 applications in month 3 to, ie after 14 months 104 patients had completed the follow-up away.

Result:

For those women who had completed 32 rPMS sessions at follow-up, the rate was now 75% (18 of 24) 8 months later. After 16 treatments it was 72.2% (26 of 36) or 68.3% in those who had now received 16 verum applications after initial placebo

treatment. In the remaining 19 women from the placebo group with 16 sessions without subsequent active therapy, the rate was 21.1% (4 of 19), (p<0.001).

This somewhat confusing result, which is due to the different intervention and placebo groups, after patients from the placebo group who were not originally treated had also received additional active applications, would be best presented in a diagram. This also led to the authors' decision to carry out the result reporting according to the so-called CONSORT statement (Consolidated Statement **Of Reporting Trials) [** 47] , which authors recommend for the preparation of reports of randomized controlled trials in the form of a checklist and a flow chart and should thus contribute to improving the reporting of clinical studies. However, it is not only the presentation that is a problem, because randomized controlled studies can also lead to distorted results if the method used is not careful enough or if the authors fail to present the essential information in a comprehensible and complete manner.

groups	**sham + sham**	**Shame + PMS**	**PMS + 0**	**PMS + PMS**
rPMS sessions	0	16	16	32
number of patients	19	41	36	24
responders	4 (21.1%)	28 (68.3%)	26 (72.2%)	18 (75.0%)

Comment:

Based on the responder rate of 75% after 2 months or about 70% after one year (68.3% + 72.2% / 2), the results are better than the rate of about 60% to be expected according to the literature. This may have something to do with the QRS Pelvicenter device used (compared to other devices), but also with differences in the treatment protocol (frequency, intensity and duration). In any case, it can be stated that the success of the therapy is much longer lasting than expected. Interestingly, the people who received 32 treatments showed a lower cure ("dry") rate after one year than those who received only 16 treatments. This may have to do with differing baseline values (ICIQ-UI SF Scores), which were 9.61 +/- 3.35 in the group of 16 and 8.78 +/- 2.23 in the group of 32. ie that the severity of the incontinence differed.

Study 6 (2017): Randomized, placebo-controlled pilot study of QRS Pelvicenter rPMS

This randomized, placebo-controlled pilot study examined how the difficult clientele of SUI patients (39), whose incontinence symptoms had not improved after more than 12 weeks of pelvic floor training (“refractory”) and who were resistant to surgery, respond to rPMS training. For this purpose, the active group (26 women) was treated with 50 Hz and the sham group (13 women) with 1 Hz once a week over a period of 10 weeks (a total of 10 sessions), with the rPMS intensity in the sham group was reduced to ≤ 42% of the active group. In the active group, the intensity was increased by 4% each time from an initial 65% of the maximum strength.

Result:

Eight patients in the active group and one in the sham group dropped out for unknown reasons. While in the active group the number of incontinence episodes, the degree of incontinence in the 24-hour pad test and the ICQ-SF as well as the QOL score decreased significantly compared to baseline ($p < 0.05$), no significant change was seen in the placebo group .

	baselines	**After 10 weeks**	**P value**
incont. episodes/week	14.4 +/- 13.9	9.6 +/- 9.5	0.049
Degree of incontinence (g per day)	15.4 +/- 15.8	9.0 +/- 12.2	0.022
ALLP*	15.9 +/- 32.3	129.8 +/- 26.6	0.002
Total ICIQ-SF Score*	15.9 +/-6.0	12.1 +/- 6.4	0.027
ICIQ QOL*	8.2 +/- 4.4	6.5 +/- 4.7	0.016

* Degree of incontinence determined by 24-hour pad test / * ALLP = Abdominal Leak Point Pressure, ie the abdominal pressure at which urine leakage occurs / ICIQ-SF = International Consultation on Incontinence Questionaire - Short Form / QOL = Quality Of Life.

What is surprising about this result is that even with a single treatment per week over 10 weeks (10 treatments), a significant improvement in SUI symptoms could be achieved. However, the previous active pelvic floor training was continued. The cause could be that the increase in "pelvic floor awareness" caused by the rPMS made the active pelvic floor training more effective.

summary

The general success rates of rPMS therapy for stress incontinence are between 41 and 81%. The success of the therapy has been proven to be stable for about a year, but in some cases significantly longer. Such results are based on RCT studies, which have a high evident validity due to their randomized, prospective, double-blind study design.

A current study with the QRS Pelvicenter stands out in particular, which was the first study on rPMS worldwide to be rated with the highest possible RCT level 5 according to the Jadad scale and which also includes the IDEAL-D framework in follow-up studies.

rPMS is proving to be an easy-to-use, target-oriented and (almost) side-effect-free urinary incontinence therapy (SUI/UI/OAB/mix) and consequently claims to establish itself as one of the first-line therapy options over the next few years .

This claim is justified because with a manageable duration of therapy of 16 to 20 applications, each lasting 15 to 20 minutes, according to evident studies, there is a clear improvement in symptoms or healing in 50 to 65 over a period of 6 to 8 weeks % of all patients can be assumed.

In addition, patients who deny an invasive procedure, or who are foreseeably unsuitable for conventional BeBo training, or who are ashamed of electrostimulation, can be offered an effective therapy solution.

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