

## PELVIC FLOOR MUSCLE TRAINING, NEGATIVE PRESSURE ABDOMINAL EXERCISE AND PELVIC ORGAN PROLAPSE SYMPTOMS: A RANDOMIZED CLINICAL TRIAL

### Hypothesis / aims of study

It has been estimated that a half of parous women lose pelvic floor support, resulting in some degree of prolapse, and that of these women 10-20% seek medical care; 40% of the general female population aged 45 to 85 years had evidence of pelvic organ prolapse (P.O.P.) of at least stage two (within 1 cm. above or below the hymen).

Risk factors include ageing, menopause, pregnancy, childbirth, denervation or weakness of the pelvic floor, and factors associated with chronically raised intra-abdominal pressure.

Conservative treatment appears to be effective in the treatment of P.O.P.: however, the role of pelvic floor muscle training (P.F.M.T.) in managing prolapse is not fully established although a recent article highlighted the effectiveness of P.F.M.T. in reversing P.O.P. and alleviating symptoms. The term "pelvic floor muscle training" encompass components of treatment (pelvic floor exercises, pelvic floor muscle bracing against increased intra-abdominal pressure and biofeedback), which are normally used together.

The aim of the current study was to evaluate whether P.F.M.T. associated with negative pressure core exercises can reverse P.O.P. of stage I or II and reduce symptoms related to P.O.P.

### Study design, materials and methods

From March 2009 to October 2009, 44 women with previously untreated prolapse of stage I or II as determined by the Pelvic Organ Prolapse Quantification System (POP-Q) were selected to participate in this individually randomized trial. Randomization was computer-generated.

For all women, symptoms of prolapse were the main presenting problem. Participants were at least 1 year post-partum. Exclusion criteria included P.O.P. stage 0 or III and more, inability to contract the P.F.M., breastfeeding, previous P.O.P. surgery, pelvic cancer, neurologic disorders, psychiatric disorders, untreated urinary tract infection, planning to become pregnant during the next 6 months and women who preferred surgery.

The study was approved by the Local Medical Ethics Committee and all subjects gave written informed consent.

At the first appointment, a standardised history - including questions on prolapse symptoms and their impact, the International Consultation on Incontinence Questionnaire (ICI-Q) urinary incontinence short form and the Italian validated version of the Prolapse Quality of Life Questionnaire (P-QOL) - was taken and both a subjective prolapse assessment and internal pelvic floor muscle assessment. A physiotherapist examined the ability to contract the P.F.M. and measured P.F.M. function. Assessment was performed in a physical therapy clinic and P.F.M. strength was measured using the modified Oxford scale.

Muscle strength was calculated as the mean of 3 maximal voluntary contractions. This method has been found to be reliable and valid if used with simultaneous observation of inward movement of perineum during pelvic floor muscles contraction. Pelvic floor muscles endurance was defined as a sustained maximal contraction and was quantified during the first 10 seconds.

Consenting women were randomized by to receive individualised P.F.M. contraction with abdominal hollowing exercises associated to a negative pressure abdominal work (intervention group, n = 23) and individualised P.F.M. contraction with abdominal hollowing exercises (control group, n = 21). Once enrolled by a physician investigator, patient groups underwent supervised training sessions; the standardised intervention given to both group consisted of outpatient appointments with a specialist women's health physiotherapist over a 24-week period: each woman was individually supervised twice a week - with session of 1 hour each - during the first 3 months and once a week during the last 3 months.

Anatomy and function of the pelvic floor muscles were taught and types of prolapse described, using diagrams and a model pelvis. Both groups were taught to contract the pelvic floor muscles correctly, and success with contracting the muscle was assessed by vaginal palpation.

A standardised lifestyle advice sheet was given to women (containing instructions on seeking advice where appropriate about weight loss, constipation, avoidance of heavy lifting, coughing and high-impact exercise). In the intervention group tailored lifestyle advice was also given by the physiotherapist on ways of reducing intra-abdominal pressure to maximise the effects of the P.F.M.T.

The outcome of primary interest was prolapse symptom severity measured via P-QOL Questionnaire: improvement was present if the women reported less frequent symptoms or less bother at 6 months posttest compared with baseline answers.

The secondary outcomes measures were prolapse severity and P.F.M. strength measured by a physician blind to the women's study group allocation.

Analysis of outcome measures was carried out in SPSS version 12 using Fisher's exact (for POP-Q stage) and Student's unpaired t tests (for prolapse symptoms and pelvic floor muscle strength) to assess the relationship between group status (intervention/ control).

### Results

Forty-seven women were randomized in the 8-month recruitment period; the mean age of the group was 53.2±4.8 years. Three women were eliminated because they were not able to perform correct pelvic floor contraction or were graded <2 by the Modified Oxford Scale. The most common type of prolapse was cystocele (85%), followed by rectocele (40%). Forty-seven percent of women had one type of prolapse only, 45% had two, and 8% had three. The most common combination of prolapse types was cystocele and rectocele (30%). At baseline, the most commonly reported symptom was the feeling of something "coming down" (83% in the intervention group and 75% in the control group).

There were no significant differences with respect to age, type or duration of prolapse, or prevalence of prolapse symptoms between the intervention and control groups at baseline.

A test of the difference in frequency and bother of prolapse symptoms from baseline to 24 weeks showed significantly greater improvement in the intervention group compared with women in the control group. Comparison between baseline and 24-week control in POP-Q values showed significantly more improvement in the intervention group (Fisher's exact test p = 0.038).

Testing the difference of P.F.M. strength and endurance there was evidence of an improvement in muscle strength in both groups,

without statistical differences between the intervention and the control group.No significant correlations between increase in P.F.M. strength and change in POP-Q values or prolapse symptoms were found.

#### Interpretation of results

In addition to improving pelvic muscles strength, we found that negative pressure core exercises performed under the supervision of physiotherapist seem to be effective in relieving frequency and bother of vaginal bulging and heaviness.

P.F.M.T. is without adverse effects, and anatomic understanding of pelvic muscles function provides a theoretical basis for strength training of the pelvic floor to be effective in prevention and treatment of P.O.P.

A Cochrane review concluded that available evidence is insufficient to understand the role P.F.M.T. may play in reducing P.O.P. but a recent study has demonstrated improvement in prolapse symptoms after P.F.M.T.

A voluntary contraction of the P.F.M. has been shown to lift the bladder base into a higher location inside the pelvic cavity, narrow the levator hiatus in the anterior–posterior and transverse direction, and prevent descent of the internal organs. The effect of abdominal hollowing training is suggested to occur via a sub-maximal co-contraction of the P.F.M. during Transversus Abdominis muscle contraction.

The basic premise behind negative pressure core exercises is that creating a vacuum within the abdominal cavity decreases intra-abdominal and intra-thoracic pressure, decreases the activity of the diaphragm and stimulates the involuntary fibers of the pelvic floor and deep core.

#### Concluding message

To date there are no RCTs investigating the effect of negative pressure core exercises training alone on pelvic floor dysfunctions: based on anatomical knowledge and evidence from RCTs, P.F.M. is the optimal muscle group to treat P.O.P. and stress or mixed urinary incontinence.

This trial seems to demonstrate that it may be additional benefit of adding negative pressure core exercises to complete the optimal rehabilitation and confer additional durability in P.O.P. of stage I or II.

#### References

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|--|---|
| <b><i>Specify source of funding or grant</i></b>                             | <b>NONE</b>   |
| <b><i>Is this a clinical trial?</i></b>                                      | <b>Yes</b>  |
| <b><i>Is this study registered in a public clinical trials registry?</i></b> | <b>No</b>   |
| <b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>                   | <b>Yes</b>  |
| <b><i>What were the subjects in the study?</i></b>                           | <b>HUMAN</b>  |
| <b><i>Was this study approved by an ethics committee?</i></b>                | <b>Yes</b>  |
| <b><i>Specify Name of Ethics Committee</i></b>                               | <b>Local Medical Ethics Committee ASL CN1 - CUNEO (ITALY)</b> |
| <b><i>Was the Declaration of Helsinki followed?</i></b>                      | <b>Yes</b>  |
| <b><i>Was informed consent obtained from the patients?</i></b>               | <b>Yes</b>  |