Pelvic organ prolapsed in women: Is training beneficial?

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SUMMARY

This study is a multicentre, randomized, controlled investigation into the efficacy of pelvic floor muscle training for the treatment of symptomatic pelvic organ prolapse (POP). Subjects were drawn from a population of patients with newly diagnosed symptomatic stage I, II or III prolapse as per the pelvic organ quantification system (POP-Q). These subjects were randomized to compare five one-on-one pelvic floor muscle training sessions over 16 weeks (intervention group) against a lifestyle advice leaflet (control group). The primary outcome was subjective improvement using the pelvic organ prolapse symptom score (POP-SS) at the beginning of the study, at 6 months, and at 12 months. Patients were also assessed for several secondary outcomes including objective improvement using POP-Q, perceived change in prolapse, interference of prolapse in everyday life, number of days with prolapse symptoms in the previous 4 weeks, uptake of further prolapse symptoms, incontinence and sexual symptoms.

A total of 377 (78%) patients completed the trial. Women in the intervention group reported significant improvement using the POP-SS at both 6 months (mean difference 2.84, 95% CI 2.05–3.63) and 12 months (mean difference 1.52, 95% CI 0.42–2.52). The subjects also showed significant improvement in secondary outcomes of the need for secondary treatment and a subjective feeling that prolapse was ‘better’. The subjects did not show significant improvement in objective measurement using POP-Q.

COMMENT

POP is an extremely common indication for urogynaecological surgery with an estimated lifetime cumulative risk of surgery of 7%–11%. While surgical treatment remains the gold standard, several conservative strategies are currently under investigation. This study examines one such conservative treatment, i.e., behavioural modification through pelvic floor muscle training. While this well-designed randomized trial generates some interesting discussion points for the value of pelvic floor training, lack of objective improvement and short follow-up times limit its value for clinical application.

For the primary end-point of self-reported symptom scores on the POP-SS, the intervention group did perform better at both 6 months and 12 months. These values exceed the value validated to be minimally clinically relevant (1.5). These findings, along with improvement in the secondary outcomes, indicate the possible value of pelvic floor training. Although this article does not speculate as to the mechanism of symptomatic improvement, one possibility is improved pelvic muscle behaviour of guarding. Constant guarding can lead to pelvic and sexual pain as well as increased bowel and bladder symptoms.

Unfortunately, although the authors were able to show subjective improvement of patients in the intervention group, as expected there was no objective improvement using the POP-Q (unlike the improvement in stress urinary incontinence with pelvic floor training). While the lack of objective findings does not diminish the value of symptom relief, they do call into question the possibility that improvement may be the result of a placebo effect rather than the intervention itself. Moreover, although 57% of patients who underwent intervention reported their prolapse to be better at 12 months, 43% of patients reported that their prolapse was the same or worse than that at the start of treatment. These numbers reflect far less improvement than that seen with open colpo-suspension, which has an estimated cure rate of 68.9%–88%. Only one randomized clinical trial has compared head-to-head the efficacy of pelvic floor muscle training against surgical management. In that study for the management of stress urinary incontinence, mid-urethral sling surgery provided a better subjective improvement (90.8% vs. 64.4%) and objective cure (76.5% vs. 58.8%). Thus, pelvic floor training may be suited for a yet unidentified subpopulation that is not ready for surgical intervention.

A second major limitation of this study is the short follow-up time. The effects of behavioural modifications such as muscle training are often criticized for their lack of durability, and that appears to be the case here. At 6 months the difference between control and intervention groups was 2.84 but at 12 months the difference had diminished to only 1.52. It is possible that the decreasing gap is the result of control patients seeking outside treatment, but such conclusions are difficult to make on post-hoc analysis. Ideally, a longer study on the secondary intervention rate after cessation of therapy should be done to investigate this issue.

The authors quote a financial cost of only £130 for pelvic floor training, and while this is much lower than the cost of surgery (anywhere from US$ 5792 to 24 161), it is of little economic benefit if it is not durable and subsequent treatments are needed.

This study provides a good beginning for the discussion of behavioural modification for the treatment of POP. Three other randomized clinical trials have compared pelvic floor training to no treatment for prolapse. While all three studies showed symptomatic benefit with intervention, two of the studies used...
analysis of under 1 year and thus do not answer the durability issue.6,7 The third trial did follow subjects for 24 months, but was only able to identify improvement in patients with severe prolapse.8 Further studies into the longevity of effect must be conducted before we can reliably recommend pelvic floor muscle training as a viable treatment. Ultimately, it comes down to patient choice as conditions of pelvic floor dysfunction are quality of life issues and each patient has a unique set of goals as opposed to the physician’s goal of anatomical correction.

REFERENCES


Classification of chronic kidney disease: Cystatin C or serum creatinine?

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SUMMARY

The impact of serum cystatin C-based estimated glomerular filtration rate (eGFR) on the staging of chronic kidney disease (CKD) and its association with outcomes was examined in this meta-analysis. Earlier studies have shown that serum cystatin C improves the prediction of eGFR as compared to serum creatinine-based eGFR. The effect of reclassification of subjects into the CKD stages by determination of eGFR based on serum cystatin C and by equations using both cystatin C and creatinine was studied in this meta-analysis. The analysis comprised 11 studies of general population-based subjects and five studies of cohorts of subjects with established CKD (creatinine-based eGFR <60 ml/minute).

The total number of subjects in this meta-analysis was 90 750 from the general population and 2960 patients with CKD. The outcomes of interest were all-cause mortality, cardiovascular mortality and end-stage renal disease (ESRD). The follow-up duration of the subjects was between 7 and 9 years in various cohorts. The baseline variable was eGFR based on either serum creatinine or serum cystatin C alone, or a combination of creatinine and cystatin C using the latest equations from the CKD Epidemiology Collaboration (CKD-EPI). These equations incorporate kidney-filtration markers (serum creatinine or cystatin C) as well as age, sex and race (black v. non-black), except for the cystatin C-based eGFR, for which the data on race were not required (Box 1).

The outcomes were analysed after appropriate adjustments for known standard risk factors. The results of the analysis showed no significant difference in the mean eGFR for both the study populations, i.e. general population cohorts and CKD cohorts. As expected, the analysis showed the well-established correlation of reduced eGFR with all-cause mortality. The threshold level at which this effect became significant was an eGFR of 88 ml/minute/1.73 m² for cystatin C-based values whereas the corresponding thresholds were 59 and 83 ml/minute/1.73 m² for the creatinine-based and combination-based determinations. The CKD-EPI creatinine equation:

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eGFR = 141 \times \min (\text{Scr}/k, 1)^{1.0} \times \max (\text{Scr}/k, 1)^{-1.209} \times 0.932^{\text{Scr}} \times 0.996^{\text{Scr}} \times 0.932 \text{ if female}
\]

Note: Scys is serum cystatin C

The CKD-EPI cystatin C equation:

\[
eGFR = 133 \times \min (\text{Scys}/0.8, 1)^{0.699} \times \max (\text{Scys}/0.8, 1)^{-1.308} \times 0.996^{\text{Scys}} \times 0.932 \text{ if female}
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