Pelvic floor muscle training can improve symptoms in women with pelvic organ prolapse and may help to reverse prolapse

Synopsis

Summary of: Braekken IH, et al (2010) Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial. *Am J Obstet Gynecol* 203: 170.e1–7. [Prepared by Nicholas Taylor, CAP Co-ordinator.]

Question: Does pelvic floor muscle training reverse pelvic organ prolapse and improve symptoms in women with pelvic organ prolapse? ***Design***: Randomised, controlled trial with concealed allocation and blinded outcome assessment. ***Setting***: A university hospital and physiotherapy clinic in Norway. ***Participants***: Women with pelvic organ prolapse were included. Key exclusion criteria were pelvic organ prolapse stage IV (complete vaginal eversion), inability to contract the pelvic floor muscles, and previous pelvic organ prolapse surgery. Randomisation of 109 participants allocated 59 to the intervention group and 50 to a control group. ***Interventions***: Both groups received lifestyle advice and were taught how to contract their pelvic floor muscles before and during increases in abdominal pressure ('the Knack'). In addition, the intervention group completed pelvic floor muscle training over 6 months. Women received up to 18 sessions supervised by a physiotherapist, a booklet and DVD showing the program, and were advised to do 3 sets of 8 to 12 close to maximum pelvic floor muscle contractions per day at home. The control group received no other intervention. ***Outcome measures***: The primary outcomes assessed at 6 months were: change in severity of pelvic organ prolapse according to the pelvic organ prolapse classification (POP-Q) system, stage 0 (no prolapse) to stage IV; position of bladder and rectum assessed by ultrasound; and improvement in frequency and bother of prolapse symptoms (feeling of vaginal bulging/heaviness) assessed on 4-point scales by questionnaire. ***Results***: 107 participants completed the study. Women in the intervention group adhered to 89% of prescribed exercise sessions and no adverse events were reported. At 6 months, more women in the intervention group (11, 19%) compared with the control group (4, 8%) had improved POP-Q stage, (Number needed to treat [NNT] 10, 95% CI > 4.2). At 6 months, women in the intervention group had a greater elevation of the bladder (mean difference 3.0 mm, 95% CI 1.5 to 4.4) and rectum (mean difference 5.5. mm 95% CI 1.4 to 7.3) compared with the control group. At 6 months more women in the intervention group had reduced frequency (NNT 3, 95% CI 1.5 to 4.6) and bother of prolapse symptoms (NNT 4, 95% CI 2.1 to 65.0). ***Conclusion***: Daily pelvic floor muscle training over 6 months can improve symptoms in women with pelvic organ prolapse and may help to reverse the development of the prolapse.

[Number needed to treat and 95% CIs calculated by the CAP Co-ordinator.]

Commentary

This is an important study for physiotherapists who treat women with pelvic organ prolapse. While physiotherapy treatment of prolapse is common (Hagen et al 2004), robust evidence to support this intervention has been lacking (Hagen et al 2006) and surgery remains the traditional treatment. This trial provides the strongest evidence yet that an effective pelvic floor muscle (PFMT) strength training program can improve prolapse symptom bother – which is the ultimate goal of the patient – as well as reduce the measured anatomical descent of the prolapse.

Clinicians may have confidence in these findings due to the rigorous study design. Clinicians may also easily access valid and reliable prolapse symptom-bother questionnaires to verify the effect of their own intervention. By measuring anatomical prolapse before and after the intervention, the authors have demonstrated morphological changes in pelvic floor tissues to explain the effect of the intervention, and to show that PFMT can reduce worsening of prolapse, thus demonstrating a secondary prevention effect. Access to the primary outcome measure used in this study, the POP-Q, will be problematic for physiotherapists not working with gynaecologists, as the POP-Q scoring system is currently not used routinely by physiotherapists. In addition, 3D real-time ultrasound, the other quantifiable measure of change in prolapse descent used in this study, is not in routine use by clinicians. A limitation to replication of the study design in the present Australian health care setting may be the frequency of physiotherapy treatments: in this study, participants attended up to 18 treatment sessions, higher than the average attendance in private or public settings in this country. However the intervention appears dose-dependant; providing a less intensive intervention may result in a less effective outcome. The challenge is for clinicians to provide effective treatment, and motivate their patients sufficiently well and for long enough for the intervention to reach a therapeutic dosage.

This study provides strong evidence to support physiotherapy-supervised PFMT as an effective intervention which may delay, or ultimately prevent, the need for surgery, when delivered at an effective dosage.

Helena Frawley
The University of Melbourne, Australia

References

Hagen S et al (2004) *Physiotherapy* 90: 19–26.

Hagen S et al (2006) *Cochrane Database of Syst Rev* CD003882.

A preventive care program for very preterm infants improves infant behavioural outcomes and decreases anxiety and depression in caregivers

Synopsis

Summary of: Spittle AJ et al (2010) Preventive care at home for very preterm infants improves infant and caregiver outcomes at 2 years. *Pediatrics* 126: e171–e178. [Prepared by Nora Shields, CAP Editor.]

Question: Does a home-based preventive care program improve cognitive, language, and motor development in very preterm infants, and mental health in their primary caregivers? ***Design***: Randomised, controlled trial with concealed allocation and blinded outcome assessment. ***Setting***: In the homes of participants in Australia. ***Participants***: Infants born at less than 30 weeks gestational age, with no major congenital brain anomalies were included. Infants were excluded if the family did not live within 100 km of the recruiting centre or if their family did not speak English. Randomisation of 120 participants allocated 61 to an education and support program group and 59 to a control group. ***Interventions***: Both groups received standard follow-up care, including access to a maternal and child health nurse and referral to early intervention services if deemed appropriate. In addition, the intervention group received nine, 90–120 minute visits over one year by a psychologist and a physiotherapist. The visits consisted of education on infant self-regulation, techniques to improve postural stability, co-ordination, and strength, and parental support. ***Outcome measures***: The primary outcomes were the cognitive, language, and motor development domains of the Bayley Scales of Infant and Toddler Development III at 2 years corrected age and the Hospital Anxiety and Depression Scale for the primary caregivers. Secondary outcome measures were child behaviour and emotional regulation assessed using the four domains of the Infant-Toddler Social and Emotional Assessment (externalising, internalising, dysregulation, and competence). ***Results***: 115 participants completed the study. At 2 years corrected age, the cognitive, language, and motor domains of the Bayley scales did not differ significantly between the groups. Three of the four domains of the Infant-Toddler Social and Emotional Assessment improved significantly more in the intervention group than in the control group at 2 years corrected age: externalising by –4.1 units (95% CI –8.2 to –0.02), dysregulation by –8.7 units (95% CI –13.2 to –4.2), and competence by 6.3 units (95% CI 0.7 to 11.8). The groups did not differ significantly on the internalising domain. The primary caregivers in the intervention group reported lower levels of anxiety and depression on the Hospital Anxiety and Depression Scale, compared with those in the control group by –2.0 units (95% CI –3.2 to –0.7 units) for depression and –3.1 units (95% CI –4.5 to –1.6) for anxiety. ***Conclusion***: A home-based preventive care program for very preterm infants and their families improved behavioural outcomes for infants and decreased anxiety and depression in primary caregivers. The program did not have any significant effects on cognitive, language, or motor development of the children at corrected age of 2 years.

Commentary

More than 12 million premature infants are born worldwide each year (March of Dimes Foundation 2009). Despite improvements in neonatal care, infants born preterm remain at high risk for neurodevelopmental impairments (Bode et al 2009). This new randomised controlled trial evaluated the VIBeS Plus program, a treatment program delivered during the first year of life aimed at improving infant cognitive, motor, and behavioural outcomes. An important additional aim was to support the mental health of the infants' primary caregivers. Compared to those in the control group, parents reported that the infants in the treatment group had better behavioural outcomes and the primary caregivers themselves had reduced anxiety and depression.

This study provides clinicians with a systematic way in which to deliver early intervention to this high risk group of infants once they leave the hospital. The VIBeS Plus program combined the best aspects of a number of other early intervention programs and was delivered by two health care professionals, physiotherapists and psychologists. The burden of care was relatively low for the health care professionals, seeing the families nine times over twelve months. Nevertheless, the long-term benefit of the VIBeS Plus program requires evaluation, particularly since the effects of some early intervention programs do not appear to be sustained (Spittle et al 2007). Moreover, although the overall effects of the program were modest, the program may have influenced growth and development in areas not assessed in this study (eg Casey et al 2009). Finally, implementing a 'preventive' program once the infants are discharged may be too late to effect changes in development long-term. Alternatively, the quality of developmental outcomes may be enhanced if the infants receive intervention continuously from birth through the first years of life (McAnulty et al 2009).

Liisa Holsti
University of British Columbia, Canada

References

March of Dimes Foundation (2009). NY.

Bode M et al (2009) *Pediatrics* 124: 866–874.

Spittle A et al (2007) *Cochrane Database Syst Rev*: CD005495.

Casey P et al (2009) *Arch Pediatr Adolesc Med* 163: 1046–1053.

McAnulty G et al (2009) *Acta Paediatrica* 98: 1920–1926.

Exercise therapy alone and exercise therapy after corticosteroid injection are equally effective after 12 weeks for moderate to severe shoulder pain

Synopsis

Summary of: Crawshaw DP et al (2010) Exercise therapy after corticosteroid injection for moderate to severe shoulder pain: large pragmatic randomised. *BMJ* 340: c3037 doi:10.1136/bmj.c3037 [Prepared by Margreth Grotle and Kåre Birger Hagen, CAP Editors.]

Question: Does subacromial corticosteroid injection combined with timely exercise and manual therapy (injection plus exercise) or exercise and manual therapy alone (exercise only) improve shoulder pain and disability in patients with subacromial impingement syndrome? ***Design***: A pragmatic randomised, controlled trial with block randomisation and group allocation by using an independent telephone randomisation service. ***Setting***: Primary care based musculoskeletal service in UK. ***Participants***: Men and women 40 years or older with unilateral shoulder pain with moderate or severe pain intensity on a 3-point scale, and with a non-capsular pattern of restriction. Key exclusion criteria were evidence of other pathological conditions in the shoulder and neck. Randomisation of 232 participants allocated 115 to the 'injection plus exercise' group and 117 to the 'exercise only' group. ***Interventions***: Both groups received standard advice to avoid activities that caused or provoked pain. The physiotherapy program started one week after the subacromial injection or immediately in the exercise only arm. The training sessions were individually adapted and comprised a selection of six mobilisation techniques and 23 progressive exercises. The patients attended as many sessions as deemed necessary by the treating physiotherapist. In addition, the intervention group received one injection of 20 mg triamcinolone acetonide mixed with 4.5 ml 1% lidocaine (lignocaine) at the mid-point of the acromion, which could be repeated after six weeks in patients with ongoing pain. ***Outcome measures***: The primary outcome was the difference in improvement in the total shoulder pain and disability index (SPADI) at 12 weeks. The secondary outcome measure was global assessment of change on a 5-point scale. ***Results***: 193 of participants completed the study, 96 in the 'injection plus exercise' group and 97 to the 'exercise only' group. At Week 12 there was no significant difference between the groups in change in SPADI scores: the mean difference between change in groups was 3.3 (95% CI −0.8 to 7.3). Improvement was significantly greater in the injection plus exercise group at Week 1 (6.6, 95% CI 4.3 to 8.8) and Week 6 (7.4, 95% CI 4.3 to 10.4) for the SPADI, with no differences at Week 24 (–2.3, 95% CI −6.8 to 2.3). For the secondary outcome a similar pattern was seen, with no significant differences at Weeks 12 and 24. For the secondary outcome a similar pattern was seen, with no significant differences at Weeks 12 and 24. ***Conclusion***: In the treatment of patients with subacromial impingement syndrome, injection plus exercise and exercise only are similarly effective at 12 weeks.

Commentary

This trial investigated whether reduced pain from a corticosteroid injection and lidocaine before starting an exercise therapy program would result in better outcome than exercise therapy only. Hence one cannot know whether it was the lidocaine or the steroid injection that gave pain relief. With this in mind, the title is somewhat misleading.

The study is well conducted. The authors have performed Rasch transformation of the main outcome instrument, SPADI. As far as we know this has previously been applied only for the SPADI disability subscale (Cook et al 2001).

The applied interventions are pertinent for this patient group (Green et al 2006). The outcomes measures (the SPADI and global assessment of change) were related only to shoulder pain and disability, and not to health related quality of life (HRQL) or work status. These are also important outcomes to consider with respect to both short and long term follow-up studies.

The treatment program was individualised, but we do not know the criteria for selecting the physiotherapists or how experienced the physiotherapists were in treating this patient group. This may have influenced the number of treatment sessions which was left to the physiotherapist to decide.

The authors compare their long term results with Hay et al (2003), but their short term results differ. This is not discussed. With this exception, the short term results were in accordance with other studies, and show that injections could be of short term benefit to patients with moderate to severe shoulder pain (Kuhn et al 2009). Long term follow-up was as reported in other studies.

Future studies could investigate exercise therapy after lidocaine injection only (without a steroid injection) for patients with moderate to severe shoulder pain, and in addition include work status and HRQL as outcomes.

Kaia Engebretsen and Helene L Soberg
Oslo University Hospital, Ullevaal

References

Cook KF et al (2001) *Arch Phys Med Rehabil* 82: 1558–1565.

Green S et al (2006) *Cochrane Database of Sys Rev*: CD001156.

Hay EM et al (2003) *Ann Rheum Dis* 62: 394–399.

Kuhn JE et al (2009) *J Shoulder Elbow Surg* 18: 138–160.