



## Prolapse: Room for Conservative Therapies Workshop 39 Tuesday 24 August 2010, 14:00 – 17:00

Time	Time	Topic	Speaker
14:00	14:10	Introduction, Case study	Helena Frawley
14:10	14:20	How does PFMT work for prolapse?	Ingeborg Hoff Braekken
14:20	14:45	Assessment: what does a physiotherapist do?	Marijke Sliker-ten Hove
14:45	14:55	Measuring success by outcomes	Ingeborg Hoff Braekken
14:55	15:25	Treatment: what does a physiotherapist do?	Ingeborg Hoff Braekken
15:25	15:55	Break	
15:55	16:10	Conservative therapies as an adjunct to surgery	Helena Frawley
16:10	16:35	Overview of the evidence for conservative management of prolapse	Suzanne Hagen
16:35	17:00	Discussion with panel	Panel
17:00		Finish	

### **Aims of course/workshop**

The aims of this workshop are:

1. To present an overview of the theory, rationale and the mechanism for pelvic floor muscle training (PFMT) for pelvic organ prolapse (POP)
2. To present an overview of the physiotherapy clinical assessment of POP, and the value of various assessment tools and outcome measures
3. To present a detailed overview of the physiotherapy treatment of POP
4. To review the rationale and findings to date of the role of physiotherapy as an adjunct to surgery for POP
5. To present the evidence for conservative therapies (pelvic floor muscle training, lifestyle modification and pessaries) in the prevention and treatment of pelvic organ prolapse (POP).

### **Educational Objectives**

This workshop will present evidence for the role of conservative therapies in the management of pelvic organ prolapse (POP). Pelvic organ prolapse is a highly prevalent condition, and predicted to increase. To date, treatment options have been limited to surgery and pessary management. This workshop will present the findings from recent research which suggests that conservative therapies have a valid and evidence-based role in the multi-disciplinary management of POP. An understanding of the theory and rationale for conservative therapies underpins the implementation of these therapies. Topics will include pelvic floor muscle assessment in women with POP and application of conservative

therapies, utilising tools accessible to all clinicians. Knowledge of these assessment tools, strategies and intervention options will enable clinicians to implement these evidence-based options for treatment of POP. Levels of evidence and recommendations for treatment will be made, with specific reference to the presenting signs and symptoms of a 'typical' case study.

## **Prolapse: Room for conservative therapies**

Workshop 39, Tues 24 August 2010, 14:00 – 17:00 hrs

**Chair:** *Dr Helena Frawley*

### **Introduction to workshop**

#### **Case study**

A case study will be used to illustrate the topic of this workshop.

Poppy, a 50 year old, para 2, presents with moderate bother of vaginal bulge. She has some co-existing mixed urinary incontinence, obstructed defaecation, and some lifestyle risk factors for prolapse. Poppy is keen to explore conservative therapies before considering surgery, and is not sure about a pessary. Poppy has received advice regarding pelvic floor muscle (PFM) exercise in the past but is not currently engaged in specific PFM training. In addition to home activities, Poppy undertakes some strenuous tasks at work and attends gym 1 x week. The rationale for PFM training for pelvic organ prolapse (POP), physiotherapy assessment and management of POP, plus the evidence for conservative therapies for POP will be presented and discussed, highlighting the options applicable to this case study.

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### **How does PFMT work for prolapse?**

*Dr Ingeborg H Brækken*

#### **Theory, rationale and mechanisms to explain how PFMT works in women with prolapse**

2 main hypotheses:

- “The knack” or “bracing”
  - Strength training builds up structural support over time
- Bø & Frawley 2007<sup>1</sup>

#### **What happens when Poppy contracts her muscles? (US video)**

##### **Bracing “closes” the pelvic floor**

Squeeze:

- From 20 to 15 cm<sup>2</sup>= 25% reduction in LH area (95% CI= 18-32) (Brækken et al 2008<sup>2</sup>)
- From 13 to 10 cm 21% reduction in muscle length (95% CI= 15-26) (Brækken et al 2008<sup>2</sup>)
- Mrs Poppy may reduce her hiatus somewhat less since POP women are more likely to have muscular impairments (DeLancey et al 2007<sup>3</sup>, Dietz & Simpson 2008<sup>4</sup>, DeLancey et al 2008<sup>5</sup>)

##### **Bracing prevent organs to descent**

PFM contraction → Anterior- cranial lift:

- Bladder neck 0.5 – 1.2cm (Thompson et al 2005<sup>6</sup>, Reddy et al 2001<sup>7</sup>, Brækken et al 2009<sup>2</sup>)
- Cervix uteri 1.1 cm (Brækken et al 2009)
- Rectal ampulla 2.0 cm (Brækken et al 2009)
- Levator plate 2.0 cm (Brækken et al 2009)

##### **More cranial than anterior movement**

The displacement was 2x, or more, greater in the cranial versus anterior direction (Brækken et al 2009).

Mrs Poppy may lift her organs less since POP women are more likely to have inability to elevate the levator plate (Thompson and Sullivan 2003<sup>8</sup>).

### **Hypothesis 1 - Bracing**

- No studies on the necessary strength or motor neuron control strategies to prevent cough induced descent
- Will the muscle strength increase?
- No – only temporary effects (Miller et al 2008<sup>9</sup>, Brækken et al 2010<sup>10</sup>)
- No changes in morphology (Brækken et al 2010<sup>10</sup>)
- However Mrs Poppy is advised to do this when she coughs, sneezes and lifts to prevent immediate descent

### **Hypothesis 2 - PFMT**

- Can PFMT build up structural support of the pelvis?
- Can the effect of repeated PFM contractions (36 to 200 per days in 1.5- 6 months) lead to
  - Elevated levator plate and “closing of the hiatus” at rest thereby elevate the organs at rest?
  - Increased muscle stiffness and thereby a more effective automatic motor unit firing leading to elevated organs during increases in IAP?

### **Background: PFM function**

- Structural support
- Localization
- Muscle thickness
- Size of levator hiatus (LH) (Standring 2005<sup>11</sup>, DeLancey & Ashton-Miller 2007<sup>12</sup>, Ghetti et al 2005<sup>13</sup>)

### **Increased muscle strength**

- Demonstrated in women with SUI (Bø et al 1999<sup>14</sup>, Mørkved et al 2003<sup>15</sup>, Hay smith et al 2007<sup>16</sup>)
- Can Mrs Poppy build up her strength, when it is known that POP women have:
  - reduced muscle strength (Samuelsson et al 1999<sup>17</sup>, Nygård et al 2004<sup>18</sup>, DeLancey et al 2007<sup>19</sup>, Brækken et al 2009<sup>20</sup>)
  - reduced muscle endurance (Brækken et al 2009)
- Yes
  - 0.5 increase (mod. Oxford) (Hagen et al 2009<sup>21</sup>)
  - 13.1 cmH<sub>2</sub>O (vaginal pressure transducer) (Brækken et al 2010<sup>22</sup>)

### **Increased muscle thickness**

- 8% hypertrophy (SUI) (Balmforth et al 2006<sup>23</sup>)
- Can it work for Mrs Poppy, when it is known that POP women have:
  - reduced muscle thickness (Hoyte et al 2004<sup>24</sup>, Chen et al 2006<sup>25</sup>)

### **Narrowing the levator hiatus**

Never been shown!

Can it work for Mrs Poppy, when it is known that POP women have:

- reduced vaginal resting pressure (DeLancey et al 2007<sup>19</sup>, Brækken et al 2009<sup>20</sup>)
  - enlarged hiatal area (Berglas & Rubin 1953<sup>26</sup>, DeLancey & Hurd 1998<sup>27</sup>, Ghetti et al 2005<sup>13</sup>, Hoyte et al 2001<sup>28</sup>, Singh et al 2003<sup>29</sup>)
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## Measuring success by outcomes: What to expect?

Dr Ingeborg H Brækken

### Outline

- Subjective outcomes
- Prolapse, bladder, bowel symptoms incl quality of life measures
- Objective
- PFM Function
- Position of the organs
- POP-Q
- Ultrasound
- Morphological changes of the PFM muscles
- Muscle thickness
- Size of hiatus
- Muscle length
- Functional changes of the PFM muscles
- Muscle length and size of hiatus at maximum Valsalva

### Standardized questionnaires

- Australian PF Questionnaire (Baessler et al 2010<sup>30</sup>)
  - POP-SS (Hagen et al 2009<sup>31</sup>)
  - ICIQ-VS (Price et al 2006<sup>32</sup>)
  - Prolapse Quality of Life (P-QoL) (Digesu et al 2005<sup>33</sup>)
  - Pelvic Floor Distress Inventory (PFDI) (Barber et al 2001<sup>34</sup>)
  - Pelvic Floor Impact Questionnaire (PFIQ) (Barber et al 2007<sup>35</sup>)
  - Symptoms and bother in POP (Mouritsen & Larsen 2003<sup>36</sup>)
  - Urogenital Distress Inventory (Shumaker et al 1994)
  - A short-form questionnaire identified genital organ prolapse (Tegerstedt et al 2005<sup>37</sup>)
- Important to cover frequencies and QoL measures. Tested for validity in the actual population.

### Scientific evidence- 4 RCTs

- Piya-Anant et al<sup>38</sup>
- Ghroubi et al<sup>39</sup>
- Hagen S et al<sup>21</sup>
- POP study (Brækken et al<sup>22</sup>, and braekken et al<sup>10</sup>)

### POP may persist with a combination of symptoms

#### Measuring success

- Can success be expected if strength training does not improve strength?
  - Can improved strength be expected if participants do not adhere to the protocol or drop out?
- Adherence/ dropout:
- Hagen et al 2009: 61% of the participants adhered at moderate and good levels. Drop out: 13 and 15% questionnaire, 11% gynaecology appointment
  - Braekken et al 2010: Home exercise=89%, PT visits = 83%. Two (1,8%) dropped out
  - Not described/ assessed: Piya-Anant et al 2003; Ghroubi et al 2008?

#### PFM Function: strength

Hagen et al 2009:

- Improvement 0.5 +/- 0.6 Oxford scale p=0.008 (Controls not tested)

Braekken et al 2010:

- Improvement: 13.1 (10.6 – 15.5) vs 1.1 (0.4-2.7) cmH<sub>2</sub>O p<0.001 Effect size: 1.21
- Not described/ assessed: Piya-Anant et al 2003; Ghroubi et al 2008?

#### PFM Function: endurance

Braekken et al 2010: Improvement: 107 (77-136) vs 8 (-7 – 24) cmH<sub>2</sub>Osec. The effect size: 0.96

### **PFM Function: resting pressure**

Braekken et al 2010:

- No significant difference in improvement between groups for vaginal resting pressure

### **Prolapse symptoms**

Piya-Anant et al 2003: not described/ assessed

Ghroubi et al 2008:

- Pelvic heaviness persisted in 19% (PFMT) vs 70% (control)  $p<0.001$

Hagen et al 2009:

- 3.5 vs 0.1 decrease in POP-SS score  $p=0.021$
- No sign changes in vaginal symptoms

Braekken et al 2010:

- 74% vs 31% reduced episodes of vaginal bulging/ pelvic heaviness episodes  $p<0.001$

### **Bladder symptoms**

Piya-Anant et al 2003: not described/ assessed

Ghroubi et al 2008:

- Significant reduction in “measurement of urinary handicap”, maximum urethral closure pressure  $p<0.001$

Hagen et al 2009:

- No significant changes in ICIQ-UI-SF

Braekken et al 2010:

- 74% vs 30% reduced numbers of SUI episodes  $p<0.001$
- 55% vs 33% reduced numbers of UUI episodes  $p=0.042$
- ICIQ-UI-SF improvement: 2.6 (95%CI: 1.0-4.3),  $p<0.001$ , Effect size: 0.62

### **Bowel symptoms**

Piya-Anant et al 2003: not described/ assessed

Ghroubi et al 2008: not described/ assessed

Hagen et al 2009:

- No significant changes

Braekken et al 2010:

- 53% vs 22% reduced numbers of flatus episodes  $p=0.002$
- No significant improvement in emptying of bowel or fecal incontinence

### **Sexual symptoms**

- ?

### **Stage of POP**

Piya-Anant et al 2003 (visualized)

- Mild degree of POP: no changes
- Severe degree of POP: 28% vs 72% worsening of POP ( $p=0.005$ )

Hagen et al 2009

- POP-Q: 5/11 (45%) vs 0/9 ( $p=0.038$ )

Braekken et al 2010

- POP-Q: 11/58 (11%) vs 4/50 (8%) ( $p=0.04$ )

### **Improvement POP-Q**

- Trend: Increasing improvement rate with increasing stage of POP ( $p= 0.06$ ) (Braekken et al 2010)
- Corresponds with Piya-Anant et al 2003

## **POP-Q**

- Valsalva → PFM are stretched and pushed in a caudal direction
- Opposite to the PFM function!
- Hence, an improvement in POP-Q may not be expected

## **3D/ 4D Ultrasound**

Used by Braekken et al 2010

### **Elevated organs**

#### **Bladder:**

- **4.3 mm** (95%CI 2.1 – 6.5),  $p < 0.001$ , Effect size: 0.75

#### **Bowel:**

- **6.7 mm** (95%CI 2.2 – 11.8),  $p = 0.007$ , Effect size: 0.65

### **Correlation with increase in PFM strength**

- Bladder elevation ( $r=0.23$ ,  $n=94$ ,  $p=0.024$ )
- Bowel elevation ( $r=0.27$ ,  $n=74$ ,  $p=0.019$ )

### **Functional changes**

- Reduced hiatal area at Valsalva  
Differences  $2.3 \text{ cm}^2$  (95%CI -0.1 – 4.8,  $p=.02$ ), Effect size: 0.43
- Reduced muscle length at Valsalva  
Differences  $11.0 \text{ mm}$  (95%CI 3.4 – 18.5,  $p=.001$ ), Effect size: 0.65

### **Morphological changes**

#### **Muscle thickness**

Differences **1.9 mm** (95%CI 1.1 – 2.7,  $p<.001$ , Effect size: 0.85)

#### **Morphological changes:**

##### **Reduced hiatal area**

- 7 % reduced hiatal area
- Differences  $1.8 \text{ cm}^2$  (95%CI 0.4 – 3.1), Effect size: 0.51

#### **Morphological changes**

##### **Shortened muscle length**

- 5 % shortened muscle length
- Differences  $6.1 \text{ mm}$  (95%CI 1.5 – 10.7,  $p=.007$ ), Effect size: 0.52

### **Functional changes**

Reduced muscle length and hiatus size at maximum Valsalva

- Indicates increased “stiffness” in the musculo-connective tissue complex
- Possible explanations:
  - amount of collagen and muscle tissue
  - changes in muscle architecture
  - altered structure of connective tissue Folland et al 2007

### **Morphological changes**

No difference occurred within the control group ( $p>0.11$ )

## **PFMT**

- Possibility to “tighten up” the pelvic floor

**Conclusion: PFMT can:**

- reverse POP (POP-Q) in some women
  - Elevate the bladder and bowel
  - Reduce mechanical, bladder and bowel symptoms
  - Increase muscle volume
  - Reduce the levator hiatus
  - Shorten PFM length
- 

**Assessment: what does a physiotherapist do?**

*Marijke C.Ph. Slieker-ten Hove, PhD, MA, PFPT*

Erasmus MC, University Medical Centre Rotterdam, The Netherlands

Pelvic Floor Dysfunction (PFD) is an umbrella term for many signs and symptoms and is often more confusing than clarifying. For example, it is too general, as it does not indicate the exact location of a particular dysfunction. This is understandable, because the pelvic floor consists of connective tissue, ligaments, fascia and muscle fibres that all have different functions, while within health care, many different specialists are involved, who have their own field of expertise, but nevertheless try to integrate their efforts. It is therefore important to focus on the different aspects of the pelvic floor and the pelvic organs, before combining these elements into a functional diagnosis. For a physiotherapist, the greatest interest is in the role of the pelvic floor muscles (PFM) in the total function of the pelvic floor and their relation to PFD. In patients with PFD, the most important application for a physiotherapist is to provide conservative treatment by working on the PFM.

The tonic (constant) contraction of the puborectalis muscle, part of the levator-ani-complex, closes the urogenital hiatus and contributes to the horizontal axis of the proximal vagina and levator plate (Strohbehn, 1998). In a woman without prolapse, in the upright position, the proximal vaginal axis is nearly horizontal, lying on the parallel levator plate. Studies have shown that as intra-abdominal pressure increases, the pelvic diaphragm contracts and maintains the position of the levator plate and horizontal vaginal axis (Nichols et al. 1970, Harris and Bent 1990, Nicols 1992). As a consequence, the uterus, vagina and rectum are pushed against the levator plate, but not through the genital hiatus. Connective tissue and striated muscles maintain the support of the posterior wall (DeLancey, 1999). Contraction of the levator ani muscles closes the vagina and relieves the connective tissue of constant load and with normally functioning levator ani muscles, no stress will occur on the midvagina support (DeLancey1992a). Therefore the diagnostic process will be intensively focussed on the PFM function.

**Assessments**

Pelvic physiotherapists take a history covering all details of the pelvic floor like bladder, bowel, uterus and sexual function questionnaires for quality of life, e.g. the Euroqol, VAS and IIQ. In addition the pelvic organ prolapse symptom score (POP-SS) (Hagen et al., 2009) can be used to score changes in pelvic organ prolapse symptoms. The pelvic floor musculature is part of the musculoskeletal system and therefore has an integrated function with abdominal and back musculature. That is why assessment of posture, pelvis and lumbar spine will be part of this assessment. For the assessment of PFM physiotherapists use a standardized assessment scale to test the pelvic floor musculature digitally, for both voluntary and involuntary contractions. In addition to this assessment, different techniques can be used: electromyography(EMG), manometry, ultra sound and in hospital settings MRI. All methods of assessment have their strengths and weaknesses, which will be briefly presented.



For physical examination of POP, the POP-Q has been developed, as a validated and internationally accepted method. This validation was based on assessment by a gynaecologist. However, recently the feasibility, inter- and intra-rater reliability of the POP-Q by physiotherapists has been demonstrated, although the physiotherapy examination time was shown to be significantly longer. Aside from the POP-Q, the question remains how to test PFM function (Stark et al., 2010). In addition to the function of the PFM, intra abdominal pressure seems to play an important role in developing and/or worsening POP or incontinence (Slieker et al., 2009). When connective tissue and reflex contraction of the PFM are not able to control the location of the pelvic organs there must be a possibility for the (conscious contracting) striated musculature to create some effect. Striated muscles can be contracted consciously and therefore can be trained with different goals. Although observed in a small group, PFM also seem to contract in voluntary or reflex co-activation with abdominal muscles (Sapsford et al., 2001, Devreese et al., 2004). Some patients present a dysfunctional co-contraction between PFM and abdominal muscles. When the patient squeezes or coughs, a caudal displacement of the pelvic floor can occur (Slieker et al., 2009). This displacement is well known but is this due to weakness or to poor coordination? Before commencing any treatment this needs to be assessed via the diagnostic process of the physiotherapist.

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## Management: what does a physiotherapist do?

*Dr Ingeborg H Brækken*

### Treatment for 'Poppy'

- Descended organs → PFMT
- Prolapse & urinary symptoms  
→ PFMT + bracing
- Information: Reduce modifiable risk factors
- Weak PFM → strength training (PFMT)
- High BMI → nutrition, physical activity
- High IAP (lifting, gym) → minimize numbers of heavy lifting + bracing
- Obstructed defecation → nutrition, fluid, toilet habits???
- If she can't contract → Adjunctive therapies
- If it doesn't work → easily removable pessary
- If this doesn't work → surgery if motivated

### Treatment

(Hagen et al 2006<sup>40</sup>, Maher et al 2007<sup>41</sup>)

460-370 B.C. "Hippocratic succession"

Apollonius von Kittum 1896<sup>42</sup>

- Surgery
- Conservative
- Pessaries (mechanical)
- Information/ Lifestyle advice
- Finding the muscles/ Correct technique
- Bracing/ "The knack"
- PFMT

### Surgery

- About 11% of all women will undergo surgery for POP or incontinence (Olsen et al 1997<sup>43</sup>)
- 41- 58% occurrence of recurrent POP (Miedel et al 2008<sup>44</sup>, Whiteside et al 2004<sup>45</sup>)
- 10 - 29% re-operations (Miedel et al 2008<sup>44</sup>, Olsen et al 1997<sup>43</sup>)

## Pessaries

- Sexual active  
→ removable ring
- POP+SUI  
→ Ring with support

- Cystocele  
→ Ring with support
- Third degree POP  
→ Donut, Gellhorn

## Information – lifestyle advice

Lifestyle advice modification

- Avoid straining (Lubowski et al 1988)
- Especially during defecation
- → hiatal ballooning (Dietz et al 2008<sup>46</sup>)
- Ultrasound video of a Valsalva Maneuver

## Information – Reduce modifiable risk factors

- High BMI (Progetto Menopausa Italia Study Group 2000<sup>47</sup>, Moalli et al 2003<sup>48</sup>)
- Increases in IAP (coughing, lifting, etc) (Rinne & Kirkinen 1999<sup>49</sup>)
- Poor PFM function (DeLancey et al 2007<sup>19</sup>, Brækken et al 2009<sup>20</sup>)
- Constipation (Arya et al 2005<sup>50</sup>, Hendrix et al 2002<sup>51</sup>)
- Avoid delay to defecate
- Fluid, nutrition
- Vigorous physical activity? (Delancey et al 2008<sup>5</sup> vs Brækken et al 2009<sup>20</sup>)
- Smoking?

## Information – Bracing/ “The Knack”

- Bracing for rises in intra-abdominal pressure
- “The Knack” when coughing or sneezing (Miller et al 2001<sup>52</sup>)
- Practice ☺

## Finding the muscles/ Correct technique

- >30% incorrect contraction (Benvenuti et al 1987<sup>53</sup>, Bump et al 1991<sup>54</sup>, Bø et al 1988<sup>55</sup>, Kegel 1948<sup>56</sup>)
- Lift and squeeze should be present (video-clip)

## Facilitation techniques

If not able to identify the muscles:

- Facilitation technique
- Tapping
- Stretching
- Information – practice for 1 week
- Adjunctive therapies

## Adjunctive therapies

Visualize the contraction:

- Pressure manometry
- Real-time ultrasound
- Surface EMG

Enhance the contraction:

- Electrical stimulation

## **PFMT**

Aim to strengthen the PFM

Image from: Lien K, Mooney B, DeLancey JOL, Ashton-Miller JA. Levator ani muscle stretch induced by simulated vaginal birth. *Obstet Gynecol* 2004 103:31-40. © Wolters Kluwer Health 2004

## **Strengthening the PFM**

### •PFMT

•Vaginal cones (VC)

•El. Stimulation (ES)

Has not been evaluated in women with POP, but SUI:

•ICI Grade B recommendations: Intensive PFMT is better than VC alone and ES alone (Hay Smith et al 2009<sup>57</sup>)

## **Protocol Piya-Anant et al 2003<sup>38</sup>**

•30 contractions per day (after a meal)

•Duration: 2 years

•Follow-up visits every 6th months

•Advised to eat more vegetables and to drink >2 liters of water per day

## **Protocol Hagen et al 2009<sup>21</sup>**

•6 sets of 20 contractions (10 slow and 10 fast) per day

•4 months

•Exercise diary

•5 PT visits

•"The knack"

•Both control and PFMT group received lifestyle advices (change from high to low impact exercise, kneel instead of squat when gardening)

## **Protocol Brækken et al 2010<sup>22</sup> (POP study)**

Strength training principles from sports science (Repetitions, Duration, Frequency, Positions)

3 sets of 8-12 contractions per day

•6 months to enhance hypertrophy

•18 PT visits

•Exercise diary

•Both control and PFMT group received lifestyle advices

## **Adherence = $\alpha\Omega$**

### **Women who do not adhere do not get stronger**

•> 80%

•Can't expect training to work if not training!

## **Which protocol is best?**

•ICI, Level A: Best results of PFMT (SUI) when:

•Supervised training

•> 3months

•Intensive training: ICI, Hay Smith et al 2009<sup>57</sup>; Bø et al 2007<sup>58</sup>

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Surgery for pelvic organ prolapse (POP) or urinary incontinence (UI) is common – an estimated 1 in 11 women undergo it (Olsen et al 1997) – and predicted to increase (DeLancey 2005). Several studies have reported both a high recurrence and high reoperative rates following POP surgery (Olsen et al 1997, Fialkow et al 2008, Clarke et al 2003), as well as the high cost involved (Subak et al 2001). Because of such issues, improved outcomes are desired. Historically, physiotherapists have provided perioperative physiotherapy for POP/UI patients to improve surgical outcomes and prevent recurrence; however, evidence to support this intervention is limited to two randomized controlled trials (RCTs) (Jarvis et al 2005, Frawley et al 2009), which have reported conflicting outcomes. Hence high quality evidence to support this intervention is limited at present. The rationale which currently guides physiotherapy clinical practice as an adjunct to surgery will be presented and clinical recommendations for management of our case study Poppy are proposed.

### Rationale for peri-operative physiotherapy

#### •Historical:

–“physiologic therapy which may be employed with preventive, curative or palliative intent, *or as an adjunct to surgical repair*” (Kegel 1956)

–Clinical practice:

•Survey of Danish gynaecologists (Ottesen et al 2001)

•Survey of Australian physiotherapists (Frawley et al 2005)

⇒Large variability exists, no established guidelines, but recommendations to clinicians (Sharpe 1998, Cook 2004, Vella and Bidmead 2006)

#### •Intervention studies:

–Findings in favour (Jarvis et al 2005)

–non-supportive findings (Frawley et al 2009)

⇒Equivocal results to date (Frawley 2010)

•POP surgery: a ‘risk’ event (Moallie et al 2003) → target patients, prophylactically?

•Parallels with general surgical rehabilitation (orthopaedic, cardio-thoracic)

•Tissue trauma and healing principles

•When to intervene: pre- / peri- / post-operatively?

•Post-operative lifting restrictions: controversy

•Resumption of activities of daily living and general exercise

•Adjunctive physiotherapy to address residual / *de novo* pelvic floor symptoms (Brubaker et al 2005, 2006)

### Associations with PFM strength and indication for POP surgery / outcomes of POP surgery:

- 317 subjects assessed pre-operatively for POP surgery. Strongest PFM: less advanced POP, smaller genital hiatus measures, less urinary symptom burden (Borello-France et al 2007)
- 358 women undergoing POP surgery: stronger pre- operatively PFM strength → ↓post- operatively POP and ↓ repeat surgery (Vakili et al 2005)

### Intra-abdominal pressure increases: what is the evidence to guide peri-operative advice?

- Weir et al 2006: Some activities commonly restricted post-operatively have no greater effect on intra-abdominal pressures than unavoidable activities like rising from a chair. How lifting is done impacts intra-abdominal pressure.

–Are current post-operative guidelines needlessly restrictive?

–Further research is needed to determine whether increased intra-abdominal pressure truly promotes pelvic floor disorders.



- O'Dell et al 2007:  
–Several exercises and activities produce less vaginal pressure rises than bearing down and coughing
- Mouritsen et al 2007:  
–Mean vaginal pressure was four to five times higher during coughing and Valsalva compared to PFM contraction, and lifting 2 and 5 kg of weight  
⇒post-operative counselling should concentrate more on treating chronic cough and constipation than restrictions of moderate physical activities

#### Two intervention studies for peri-operative PFMT and lifestyle advice:

##### *Jarvis et al 2005:*

This RCT investigated the role of peri-operative physiotherapy in women undergoing surgery for POP and/or incontinence. 30 women underwent preoperative physiotherapy and 30 others had no physiotherapy prior to their POP/UI surgeries. Outcome measures were: paper towel test, urinary symptom specific health and quality of life questionnaire, frequency/volume chart and pelvic floor muscle manometry. Women were followed up for 3 months. Results were presented for both POP / UI groups combined. Both groups showed improvement in urinary continence. Significant group differences were noted in the quality of life questionnaire (P = 0.004), urinary symptoms (P = 0.017) and maximum pelvic floor muscle squeeze on manometry (P = 0.022). Diurnal frequency analysis indicates that there is a significant difference in favour of the treatment group (P = 0.024). Conclusion: Routine pre and post operative physiotherapy interventions improve physical outcomes and quality of life in women undergoing corrective surgery for urinary incontinence and or pelvic organ prolapse.

##### *Frawley et al 2010:*

This RCT investigated the effect of a pre- and post-operative physiotherapy-supervised pelvic floor muscle (PFM) training program in women undergoing surgery for prolapse or hysterectomy. Methods: Participants were assessed pre-operatively, and at 3, 6, and 12 months post-operatively by a blinded physiotherapy assessor. Following randomization, participants were allocated to a control group (CG) which included “usual care” (as provided by the surgeon and the hospital staff), or a treatment group (TG) which included one pre-operative and seven post-operative treatment sessions over 12 months. Primary outcomes were bladder and prolapse symptoms, measured by the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ). Results: Fifty-one participants were randomized. The 12-month post-operative findings showed there was no difference in the prevalence of the primary outcomes (ORs 1.2, 1.3). There were no significant differences between groups on the change scores of the UDI (mean: 44.1 [5.1]; 54.0 [5.4], P ¼ 0.20) nor the IIQ (median: 0.0 [9,14]; 10.0 [5,19], P ¼ 0.09). The repeated measures analyses also demonstrated no significant changes. Conclusion: The program tested did not improve bladder or prolapse symptoms in this trial. Reasons may include the effectiveness of surgery alone, wide variance in data, small sample size, insufficient training by the TG, and PFM training by the usual care group.

#### A trial of physiotherapy before surgery?

Current guidelines recommend PFMT before a decision is made for UI surgery (Hay-Smith et al 2009). This is supported by the strong evidence for PFMT to treat UI. The evidence to support PFMT +/- lifestyle advice for the treatment of POP is emerging and has been covered by other speakers today. The strength of this recommendation will guide whether physiotherapy should be offered as a trial pre-POP surgery. Consideration of the current outcomes of POP surgery and symptom recurrence (Olsen et al 1997, Fialkow et al 2008), the natural regression / remission of POP which has been observed (Bradley et al 2007, Handa et al 2004), the cost of POP surgery (Subak et al 2001), and the associations which have been observed between PFM strength and less advanced POP (Samuelsson et al 1999, Borello-France et al 2007), and reduced recurrence of POP symptoms and need for

further surgery (Vakili et al 2005), suggest our case study Poppy may be advised to consider a trial of PFMT before considering surgery.

#### Physiotherapy as an adjunct to surgery?

Although there is a sound pathophysiologic rationale for the effect of PFMT as an adjunct to POP surgery, only two studies have been published to date, with conflicting findings emerging. Based on these, it is possible that should our case study Poppy proceed to surgery, she may have an improved result if she undertakes PFMT + lifestyle modification of pre-existing risk factors. The level of evidence to support this intervention is currently rated as 2 and Grade of Recommendation as C (Hay-Smith et al 2009). With 2 further trials underway to investigate this question, it is hoped that future published findings will be able to definitely answer this question.

#### Future research:

- Barber et al 2010: OPTIMAL trial
- McClurg et al, The SUPER Trial:  
Physiotherapy Research Foundation, United Kingdom. Title: SUPER: SURgery and Physiotherapy for prolapsE to avoid Recurrence: a feasibility study.  
D. McClurg, S. Hagen, P. Hilton, C. Dolan, A. Monga, H. Frawley.

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## **Overview of the evidence for conservative management of prolapse**

*Professor Suzanne Hagen*

- **ICI Committees Paris, France - July 5-8, 2008**
- Evidence available
- Levels of evidence
- **Level 1 evidence (incorporates Oxford 1a, 1b)** usually involves meta-analysis of trials (RCTs) or a good quality RCT
- **Level 2 evidence (incorporates Oxford 2a, 2b and 2c)** includes “low” quality RCT or meta-analysis (with homogeneity) of good quality prospective ‘cohort studies’
- **Level 3 evidence (incorporates Oxford 3a, 3b and 4)** includes: good quality retrospective ‘case-control studies’ with appropriate matching (e.g. for age, sex etc). good quality ‘case series’ where a complete group of patients all, with the same condition/disease/therapeutic intervention, are described

- **Level 4 evidence (incorporates Oxford 4)** includes expert opinion where the opinion is based not on evidence but on 'first principles' (e.g. physiological or anatomical) or bench research

#### Cochrane reviews on prolapse treatment

- Surgery *Maier, Feiner, Baessler, Glazener. 2010*
  - 40 trials, 3773 women
  - Some evidence re vault, anterior, posterior repair
  - Not enough evidence on most types of common prolapse surgery nor about the use of mesh or grafts
- Mechanical devices *Adams, Thomson, Maier, Hagen 2004*
  - No published trials
  - Not enough evidence about the effects of mechanical devices (pessaries) on managing prolapse
- Conservative management *Hagen, Stark, Maier, Adams 2006*
  - 3 trials (1 sizeable)
  - Insufficient evidence to guide practice
- Oestrogen
  - Ismail SI, Bain C, Glazener CMA, Hagen S. Oestrogens for treatment or prevention of pelvic organ prolapse in women (Protocol). *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD007063. DOI: 10.1002/14651858.CD007063.
  - Lifestyle: risk factors for prolapse
- Familial transmission *Tegerstedt O&G 2009*
- Ethnicity *Whitcomb AJOG 2009*
- Socioeconomic factors
- Occupation/heavy lifting *Tegerstedt O&G 2009*
- Obesity *Whitcomb IJU PFD 2009*
- Vitamin D *Badalian O&G 2010*
- Obstructed defaecation *Tegerstedt O&G 2009*
- Hysterectomy
- Childbirth/CS/obstetric factors *Larsson 2009*

#### Lifestyle interventions: prevention

- No prospective studies
- Evidence of association between prolapse and
  - Heavy lifting/strenuous physical activity (LE 3)
  - Being overweight (LE 3)
  - Constipation (conflicting findings, poor quality)
  - Anaemia (one study)
- Potential for prevention trials
- Long-term follow-up required

#### Lifestyle interventions: treatment

- No studies have been identified to date that evaluate the effectiveness of lifestyle interventions in the treatment of women with prolapse

#### PFMT: prevention

- Relationship between pelvic floor function and prolapse (LE 2):
  - Borello-France 2007
  - Braekken 2009
  - Slieker Ten-Hove 2009
  - Moen 2009
- Secondary analysis:

- Glazener ICS 2010 – ProLong Study, prolapse 12 years after childbirth, trial of PFMT
- Braekken 2009, 2010 – trial subgroup of non-symptomatic women, effect of PFMT?

#### PFMT: treatment

- Overview
  - Piya-anant
  - Ghroubi
  - Hagen
  - Braekken (LE 1)
- Cochrane review being updated
  - Conservative management *Hagen, Stark, Maher, Adams 2006*
    - 3 trials (1 sizeable)
    - Insufficient evidence to guide practice

#### Piya-anant et al 2003

- Elderly (60yrs+) community sample, Thailand
- Anterior prolapse
- Symptomatic?
- 330 intervention/324 control
  - unspecified PFExs training
  - dietary advice
- 6 and 24 month follow-up
- No objective prolapse measurement
- PFExs effective in women with severe prolapse
  - @ 24mths 72.2% worse in control vs 27.3% in intervention

#### Ghroubi et al 2008

- 47 women with stage I or II cystocele, randomised to PFM exercises + healthy living advice or control group
- Outcomes: clinical examination, the “Measurement of Urinary Handicap” (MUH) scale, urodynamic tests, the Ditrovie quality of life scale, patient satisfaction
- immediately post-treatment, pelvic heaviness persisted in 5 (19%) in treatment group vs 14 (70%) in the control group ( $p < 0.001$ )
- significant differences in quality of life and urodynamic measures in favour of treatment group
- 20 women from the treatment group retained benefits two years after the treatment had ceased
- Hagen et al 2009 - methods
- feasibility trial, 47 women randomised to PFMT ( $n=23$ ) or control ( $n=24$ ) group
- stage I or II symptomatic prolapse of any type, 2 UK centres.
- Intervention: 5 physiotherapy appointments over 16 weeks, with an individually-prescribed daily PFM exercise programme. Control women received a prolapse lifestyle advice leaflet by post only.
- Outcomes: blinded POP-Q; prolapse-related symptom severity and quality of life; PFM strength (modified Oxford scale) intervention group only.
- Follow-up at 6 months

#### Hagen et al 2009 - results

- PFMT group more likely than controls to have an improvement in prolapse stage (45% vs 0% improved, Fisher’s exact test  $p=0.038$ ).
- Intervention group had significantly greater improvement by 6 months than controls in their prolapse symptom score (mean score decrease 3.5 versus 0.1,  $p=0.021$ ).

- PFMT group more likely to report their prolapse was better now than at the start of the study (63% vs 24% at 6 months,  $p=0.012$ )
- A significant improvement in PFM strength was detected in the intervention group; mean muscle strength increased by 0.5 on the modified Oxford scale (95% CI 0.2 to 0.8,  $p = 0.008$ )

Braekken et al 2009, 2010 - methods

- RCT of 108 women, stage I, II or III
- Intervention:  $n=59$ , instructed in PFMT for 6 months with home exercise
- Control:  $n=50$
- Both groups: lifestyle advice, “the Knack”
- Outcomes: POP-Q, symptoms, ultrasound
- Follow-up at 6 months

Braekken et al 2009, 2010 - results

- Improved POP-Q by 1 stage: 19% PFMT vs 8% control
- Position of bladder and rectum significantly higher in PFMT group
- PFMT group had:
  - Increased pubovisceral muscle thickness
  - Decreased hiatal area at rest/valsalva
  - Shortened muscle length at rest/valsalva
  - Increased muscle stiffness
- Relevant ongoing research - PFMT

Treatment: POPPY Trial (Hagen)

- PFMT or prolapse ( $n=448$ )
- 16 week/5 appointment intervention
- 1 year follow-up symptoms and severity
- Trial to report 2011

Prevention: PREVPROL (Hagen)

- Prevention of symptoms in non-symptomatic women with some vaginal laxity
- Recruited from longitudinal cohort

Picture of pessaries (support and space –occupying)

- Pessaries: treatment
- Cundiff: RCT of Gellhorn vs ring (LE 2)
- Lukban: uncontrolled study of Colpexin sphere
- Kapoor: uncontrolled study of pessary vs surgery
- ATLAS Trial: PFMT +/- pessary for UI (March 2010) – prolapse women included?

Cochrane review – to be updated

- Mechanical devices *Adams, Thomson, Maher, Hagen 2004*
  - No published trials
  - Not enough evidence about the effects of mechanical devices (pessaries) on managing prolapse

Cundiff et al 2007 - methods

- multi-centre crossover RCT, ring with support vs Gellhorn pessary.
- 134 women randomised; 71 to ring pessary with support and 63 to Gellhorn, followed by crossover to the second type of pessary, ring with support ( $n=54$ ) or Gellhorn ( $n=54$ ).
- stage II or greater symptomatic prolapse, no prior pessary experience.
- 48% had stage II, 42% stage III and 10% stage IV prolapse.
- 51% had anterior prolapse.

- Mean age 61 years, most women parous and post-menopausal.
- no significant differences between groups at baseline.
- fitted with 1<sup>st</sup> pessary for 3 months, then 2<sup>nd</sup> pessary for 3 months.
- Follow-up: during each 3-month period data collected at 1, 6 and 12 weeks from women with successful fit.
- 1 year appointment to discuss pessary continuation/other treatment.
- Outcomes measured at enrolment and 3-months: POP-Q, PFDI, PFIQ, sexual function questionnaire.

#### Cundiff et al 2007 - results

- Combining the two trial periods there were complete data on the ring pessary from 94 women, on the Gellhorn from 99, and on both pessaries from 85.
- statistically significant improvements in the majority of PFDI and PFIQ scale scores for both pessaries, including the prolapse specific sub-scores (POPDI for symptoms and POPIQ for impact).
- no differences between pessaries in improvement in these two sub-scores (POPDI,  $p=0.99$ ; POPIQ,  $p=0.29$ ).
- all POPDI sub-scores showed clinically significant improvements for both pessaries. Only for the Gellhorn were there clinically significant improvements in impact of prolapse symptoms (POPIQ), and only then for the physical sub-score and the total POPIQ score.
- Women who were highly satisfied with the Gellhorn also had improvement in a range of symptoms including the POPDI score; no similar significant association was found for the ring pessary with support.
- Relevant ongoing research - pessaries

#### OPTIMAL Trial (Barber)

- Vault surgery +/- PFMT
- Trial to report 2012

#### PEPPY Study (Hagen)

- Feasibility study
- PFMT +/- pessary for prolapse
- Case study – Poppy

#### Would lifestyle modification help Poppy?

- We can't make E-B recommendations but epidemiological studies suggest obesity, heavy lifting and possibly constipation may play a role, and Poppy could be advised on these as appropriate

#### Would PFMT help Poppy?

- Most rigorous evidence to date suggests that PFMT would help reduce the anatomical prolapse and the associated symptoms after 6 months

#### Would pessary help Poppy?

- Preference is a factor, as is the skill/patience of the clinician. If she were to opt for a pessary no difference between ring with support and Gellhorn

#### If Poppy was to opt for surgery, would PFMT as an adjunct help?

- We can't make evidence based recommendations. Small controlled trials to date haven't shown an effect. Larger trial of surgery +/- PFMT in vault prolapse is underway.

#### Conclusions re. Conservative options

- What do we have strong evidence for?

- Association between pelvic floor muscle function and prolapse
- PFMT, supervised 6 month programme
- Ring with support and Gellhorn
- What do we have little/no evidence for?
  - Lifestyle modifications eg. Weight loss
- What should evidence-based advice be for our patients?

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## **Panel Discussion**

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