Prediction & Prevention of Pelvic Floor Disorders in the Developed World – UR-CHOICE!

Don Wilson, on behalf of the UR-CHOICE Study Group
Emeritus Professor of Obstetrics & Gynaecology
Associate Dean (Nelson/Marlborough)
University of Otago, New Zealand, Aotearoa
“Just about the worst thing that can happen to a woman in this world is to develop an obstetric fistula that leaves her trickling bodily wastes and shunned by everyone around her.”

Nicholas D. Kristof
Pulitzer Prize Winner, New York Times Columnist
Obstetric Fistula

- 2,000,000 women living with a fistula
- 50,000-100,000 new cases per year
- Approximately 15,000 cases being repaired each year

Shane Duffy (Personal Communication)
Pelvic Floor Disorders

• Urinary Incontinence
• Faecal Incontinence
• Pelvic Organ Prolapse
Pelvic Floor Dysfunction

• Significant effect on quality of life for a large number of women
  – “Epidemic proportions in later life” (MacLennan et al 2000)

• Significant cost implications for Health Services

• Great importance to identify possible aetiological factors with a view to subsequent prevention/reduction of its impact
Prevalence of Urinary Incontinence and Distribution by Parity

Percent incontinent

Parity

0 1 2 3 4 5+

6 22 18 19 19 21

regular incontinence
? Pregnancy or ? Parturition

PELVIC FLOOR DYSFUNCTION
Obstetric demographics in developed world changed over past 40 years

- Women older when have first baby
- Women’s BMI’s are greater
- Babies are heavier
- All risk factors for PFD!

Women are having fewer babies
Pelvic Floor Dysfunction

- Prevention of PFD major priority in women’s health in the developed world
- Identification of women “at risk” is a key element in current prevention strategies.
- One of the major barriers to effective prevention is our inability to effectively identify “at risk” women.
Current Main Prevention Strategies

• Caesarean Section and other delivery modes
• Pelvic floor muscle training
• Modifiable risk factors/lifestyle interventions
“I would definitely consider paying to have one [Caesarean Section]. I don’t think natural childbirth is a great system. I’m worried about stitches, long-term incontinence and a ruined sex life afterwards. I’d rather not take any risks.”

(36 year old journalist, *Cosmopolitan*)
Birth by Design: Are Celebs Too Posh to push?

NEW YORK — Celebs - as usual on the leading edge — are rumored to be at the forefront of a growing movement among new moms: pre-scheduled, elective Caesarean Sections.

By Jennifer D'Angelo
www.foxnews.com
Unintended benefits?

Can pelvic floor dysfunction be prevented by caesarean section? Findings from the ProLong and other epidemiological studies.

Pelvic floor dysfunction (PFD) in women results in the combination of some or all of the following conditions: urinary incontinence (UI), faecal incontinence (FI) and pelvic organ prolapse (POP). It also influences sexual function.

It is a very common problem, with over 46 per cent of women having some form of major pelvic floor dysfunction and is of epidemic proportions in later life.\(^1\) Approximately 11 per cent of women undergo surgery for this condition during their lifetime, seven per cent for prolapse alone.\(^2\) In the USA, POP is thought to lead to over 200,000 surgical operations a year, resulting in an annual expenditure of US$1 billion.\(^3\)

Pelvic floor dysfunction surgery numbers are likely to increase substantially as the population longitudinal study ProLong (PROlapse and incontinence LONG- term research study). This commenced in 1993–94 and involved the Universities of Otago, Birmingham and Aberdeen in the UK. This is the largest ongoing prospective study in this field and involves a cohort of nearly 8000 women of whom just under 50 per cent returned questionnaires at three months, six and 12 years after delivery.\(^4\) Women were also examined at the 12-year follow up.\(^5\) It is planned to carry out the 20-year follow up in 2014. In this article the 12-year results of the ProLong study will be presented and compared with other epidemiological studies, with particular emphasis on whether caesarean section is protective for subsequent PFD.

**Urinary incontinence**

At 12 years after delivery, urinary incontinence is very common, with just over 50 per cent of women having this complaint. Women who delivered exclusively by caesarean section were less likely to have UI in comparison to women who delivered vaginally, (vaginal delivery 55 per cent versus caesarean 40 per cent, OR 0.46:95 per cent CI 0.37-0.58), but not if they had a combination of caesarean and spontaneous vaginal births.\(^6\)

A similar reduction is seen at 20 years after delivery in the Swedish National Survey of pelvic floor dysfunction, the SWEdish Pregnancy Obesity Pelvic floor (SWEPoP) study. This involved just over 5000 primiparous women who delivered in 1985–88 with no further births.
ProLong: Longitudinal Study of Pelvic Floor Dysfunction and Childbirth

Universities of Otago, Aberdeen, and Birmingham
Funded by: WellBeing of Women and University of Otago

- All deliveries within 12 months (1993-94)
- 7883 participated 3 months after index birth
- 3638 followed up 12 years after delivery
The prevalence of urinary incontinence 20 years after childbirth: a national cohort study in singleton primiparae after vaginal or Caesarean delivery

- Swedish Pregnancy, Obesity and Pelvic Floor (SWEPOP) Study linked Medical Birth Register data to a questionnaire about UI sent in 2008

- 5236 Singleton Primiparae who delivered in the period 1985-1988 with no further births

Gyhagen et al BOG 2012
Role of Caesarean Section on Prevention of PFD – Summary of Evidence

**Urinary Incontinence**

Partial protection but prevalence still high:

- **ProLong** 12 years after delivery
  
  VD 55% CS 40% (OR 0.46, 95%, CI 0.37-0.58)

- **SwePOP** 20 years after delivery – Primipara
  
  VD 40% CS 29% (OR 1.67, 95% CI 1.45-1.91)

- No difference between elective and emergency Caesars
Role of Caesarean Section on Prevention of PFD – Summary of Evidence

Faecal Incontinence
• No evidence of reduced likelihood of FI in ProLong Study with Caesar at 12 years after delivery
• Similar findings of lack of longterm effect on FI was noted in updated Cochrane Review with Caesar

Forceps/Vacuum
• Risk of long term faecal incontinence is significantly higher after having had one or more forceps deliveries (OR 2.08 95% CI 1.53-2.85)
Role of Caesarean Section on Prevention of PFD – Summary of Evidence

POP:

- Reduced risk of POP symptoms VD 14.8% CS 6.3% (OR 2.55, 95% CI 1.98-3.28)
- Reduced risk of objectively measured signs of prolapse VD 29% CS 5% (OR 0.11, 95%, CI 0.03-0.38)
- Reduced risk of POP surgery
  VD vs CS Hazard Ratio 9.2 (95%, CI 7-12)
  Forceps vs CS Hazard Ratio 20.9 (95%, CI 20.9, 95%, CI 5.5-79.9)

Partial protection for POP and to a lesser degree UI
Role of Elective Caesarean Section on Prevention of Pelvic Floor Dysfunction – Conclusion

• Controversial!
• Given the associated risks (especially multiple repeat Caesarean deliveries) it is unlikely that elective Caesarean Sections is an effective prevention strategy for most women
• A strategy of offering elective Caesarean Section to women who are at substantially higher than average risk of PFD may be a more appropriate and effective prevention strategy
• ?What risk threshold

E. Jelovsek et al, AJOG, 2017
Current Main Prevention Strategies

• Caesarean Section and other delivery modes
• Pelvic floor muscle training
• Modifiable risk factors/lifestyle interventions
‘Bodybuilding is a very mental sport — you have to prepare yourself mentally to withstand the rigors of intense bombing and blitzing.’

— Mike Mentzer
There's only one way to cure stress incontinence forever.

Get Pelvic Floor Muscles of Steel! ....The NordicSphincter

Call 1-800-Sphincter For a Free Brochure.
(no salesman will call)
Cochrane Review Antenatal PFMT in Continent Women

- 38 trials of 9892 women
- 62% less likely to have UI in late pregnancy
- 29% less likely to have UI at 3-6 months postpartum
- Insufficient evidence for effect greater than 6-12 months postpartum

Woodley SJ et al 2017
Cochrane Review Antenatal PFMT in Continent Women - Conclusions

“Targetting continent antenatal women early in pregnancy and offering a structured PFMT programme may prevent the onset of urinary incontinence in late pregnancy and postpartum.”

Woodley SJ et al 2017
A multicentre randomised controlled trial of a pelvic floor muscle training intervention for the prevention of pelvic organ prolapse


NMAHP Research Unit, Glasgow; Health Services Research Unit, Aberdeen; University of Birmingham; Dunedin School of Medicine, University of Otago; Birmingham Women's Hospital; Aberdeen Royal Infirmary; Yunus Centre, Glasgow Caledonian University

Funded by Wellbeing of Women

Women in the Intervention group more likely to report doing PFM exercises (77% v 53% P <0.001) and to say they felt a health-related benefit (44.2% v 9.8% P <0.001) compared to Controls.

Significantly lower POP-SS score at 2 years in the Intervention Group compared to Control P = 0.004

Further treatment for prolapse symptoms was less common in the Intervention Group (5.9% v 14.4% P = 0.007)

Rate of GP consultations related to prolapse symptom was lower in the Intervention Group (2.9% v 12.2% P = 0.01).

Women should be recommended to undertake PFMT even before they have bothersome symptoms
PINT RCT. Results – woman performing pelvic floor muscle training

Percent

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>78%</td>
<td>48%</td>
</tr>
<tr>
<td>P=0.037</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 years</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 years</td>
<td>53%</td>
<td>50%</td>
</tr>
<tr>
<td>NS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Glazener et al. 2014)
Pelvic floor muscle training to prevent pelvic floor dysfunction

• It works!
• Challenge – How do we increase motivation, and adherence to PFMT?
Current Main Prevention Strategies

- Caesarean Section and other delivery modes
- Pelvic floor muscle training
- **Modifiable risk factors/lifestyle interventions**
Modifiable Risk Factors/Lifestyle Interventions Preventing Urinary Incontinence

- Women should aim at normal weight before pregnancy (Grade A)
- Aim at regaining pre-pregnancy weight postpartum (Grade B)
- Constipation should be avoided during pregnancy and postpartum (Grade C)

Current Main Prevention Strategies

- Caesarean Section and other delivery modes
- Pelvic floor muscle training
- Modifiable risk factors/lifestyle interventions

Influenced by UR-CHOICE “Score” giving personalised “Risk”/likelihood of developing PFD (UI, FI & POP)
IUGA Debate

“This house believes that instrumental delivery should be abandoned in favour of Caesarean section”

Profs Don Wilson & Jim Dornan
UR-CHOICE: can we provide mothers-to-be with information about the risk of future pelvic floor dysfunction?

Don Wilson · James Dornan · Ian Milsom · Robert Freeman

Received: 13 January 2014 / Accepted: 13 March 2014
© The International Urogynaecological Association 2014

Abstract Vaginal childbirth is probably the most important factor in the aetiology of pelvic floor dysfunction (PFD) and results in the combination of some or all of the following conditions: urinary (UI) and faecal (FI) incontinence and pelvic organ prolapse (POP). Up until now, it has been difficult to counsel women antenatally regarding risk factors for subsequent PFD, as there has been little good-quality, long-

Keywords Pelvic floor dysfunction · Urinary incontinence · Faecal incontinence · Pelvic organ prolapse · Vaginal delivery · Caesarean section · Prediction

Introduction
Moderately robust epidemiological data 12 & 20 years after delivery & pathophysiological data using risk factors

Major risk factors for subsequent PFD:

<table>
<thead>
<tr>
<th>U</th>
<th>UI before pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>Race/Ethnicity</td>
</tr>
<tr>
<td>C</td>
<td>Childbearing started at what age</td>
</tr>
<tr>
<td>H</td>
<td>Height of mother</td>
</tr>
<tr>
<td>O</td>
<td>Overweight (weight, BMI of mother)</td>
</tr>
<tr>
<td>I</td>
<td>Inheritance (family history)</td>
</tr>
<tr>
<td>C</td>
<td>Children (number of children desired) or Caesar/delivery mode for postpartum “score”</td>
</tr>
<tr>
<td>E</td>
<td>Estimated fetal weight</td>
</tr>
</tbody>
</table>

Wilson, D, Dornan, J, Milsom, I, Freeman, R,
(International UrogynaecologyJournal, April 2014)
Prediction Models for Postpartum Urinary and Fecal Incontinence in Primiparous women

Jelovsek JE, Piccorelli A, Barber MD, Tunitsky-Bitton, Kattan MW

Vaginal Delivery – Risk of Any Pelvic Floor Disorder (AnyPFD)

Aim:

To Produce normograms that accurately generate individualized prognostic estimates of postpartum UI and FI
Predictive Modelling Co-operation

SwePOP Study Group
Sahlgrenska Academy, Gothenburg
Maria Gyhagen, Jwan Othman, Björn Areskoug, Ian Milsom

PROLONG Study Group
Aberdeen, Glasgow and Otago
Don Wilson, Charis Glazener, Suzanne Hagen, Andrew Elders

CLEVELAND CLINIC Group
Cleveland
Matt Barber, Eric Jelovsek, Michael Kattan, Kevin Chagin
Study Population

Data from 2 longitudinal, prospective cohorts

1. **Swedish Pregnancy, Obesity and Pelvic Floor Study (SwePOP)**
   - Only Primiparous women delivered 1985-1988 (n = 9423)
   - Swedish Medical Birth Register data
   - 4991 linked to Postal Questionnaire 20 years after delivery

2. **ProLong study from UK/New Zealand**
   - All deliveries w/n 12 months (1993-94)
   - 7883 participated 3 months after index birth
   - Aberdeen (UK), Birmingham (UK), Dunedin (New Zealand)
   - 3638 followed up to 12 years after delivery

Study Cohort: 8624

Gyhagen M, Bullarbo M, Nielsen T, Milsom I. BJOG 2013
Hypotheses

• Multiple regression models can be developed to predict the likelihood of developing PFDs 12-20 years after delivery that:
  
  ❑ Discriminate better than chance women who are at high risk from women who are at low risk
    
    Concordance Index
    
    \[ I = \begin{cases} 
      1 & \text{perfect discrimination} \\
      0.5 & \text{no better than chance} 
    \end{cases} \]
  
  ❑ Reasonable calibration and are internally and externally validated.
Women delivering in the first half of the cohort time period

Women in Second Half

Training

Test Set

Predictive Models

Actual Outcomes
METHODS

• Training Set
• Multiple logistic models
• Harrell’s “Model Approximation” process of backwards elimination
• Best parsimonious model

• Model accuracy was measured as discrimination using a concordance index and calibration using visual plots were created.

• Online calculators
Results

Model Discrimination
Overall all models were able to discriminate better than chance and able to discriminate risk 51-75% of the time for each temporal validation set. 

Before delivery, 12 & 20 year concordance indices for bothersome or receiving treatment were:

- POP (0.570, 0.627)
- UI (0.653, 0.689)
- FI (0.618, 0.676)
Other Predictive Models currently used in Clinical Practice

• National Cancer Institute Gail Model for Prediction of Breast Cancer Risk – Concordance Index 0.59

• Framingham Cardiovascular risk model – Concordance Index 0.72
## Risk Factors

- Maternal age at delivery
- Number of previous births
- Maternal pre-pregnancy weight
- Maternal height
- Estimated birthweight
- Family History of UI/POP
- Urinary Incontinence PRE or DURING Pregnancy

## Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Route of Delivery</th>
<th>Bothersome/Treatment</th>
<th>Average risk of bothersome/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic organ prolapse</td>
<td>Vaginal</td>
<td></td>
<td>9%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td></td>
<td>7%</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td>Vaginal</td>
<td></td>
<td>28%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td></td>
<td>24%</td>
</tr>
<tr>
<td>Fecal Incontinence</td>
<td>Vaginal</td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>Any pelvic floor disorder</td>
<td>Vaginal</td>
<td></td>
<td>37%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td></td>
<td>32%</td>
</tr>
</tbody>
</table>

## UR-CHOICE Pelvic Floor Disorders Risk Calculator

How can we counsel patients?

Case 1: lower risk primigravida

- 28 year old
- Primigravid woman
- 150 pounds, 5 feet 4 inches tall
- EFW = 7 pounds 2 ounces
- Fetal HC = 35 cm
- No history of UI before or during pregnancy
- No family history of POP, UI or FI
Online Calculator http://riskcalc.org/UR_CHOICE/
UR-CHOICE Pelvic Floor Disorders Risk Calculator

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Route of delivery</th>
<th>Bothersome /treatment</th>
<th>Average risk of bothersome/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic organ prolapse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td></td>
<td>4%</td>
<td>9%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td></td>
<td>15%</td>
<td>20%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td>10%</td>
<td>15%</td>
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<tr>
<td>Faecal Incontinence</td>
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<td></td>
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<tr>
<td>Vaginal</td>
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<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Any pelvic floor disorder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td></td>
<td>20%</td>
<td>27%</td>
</tr>
<tr>
<td>C-Section</td>
<td></td>
<td>12%</td>
<td>18%</td>
</tr>
</tbody>
</table>

“C-Section reduces your risk of any bothersome/treatment PFD 20 years after delivery by 8%”
How can we counsel patients?

Case 2: higher risk primigravida

- 28 year old
- Primigravid woman
- 150 pounds, 5 feet 4 inches tall
- EFW = 7 pounds 2 ounces
- Fetal HC = 35 cm
- UI before pregnancy
- Positive family history of POP and UI
Online Calculator http://riskcalc.org/UR_CHOICE/
UR-CHOICE Pelvic Floor Disorders Risk Calculator

<table>
<thead>
<tr>
<th>Higher Risk Primigravida</th>
<th>Route of delivery</th>
<th>Bothersome /treatment</th>
<th>Average risk of bothersome/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic organ prolapse</td>
<td>Vaginal</td>
<td>20%</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>C-Section</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td>Vaginal</td>
<td>&gt;30%</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>C-Section</td>
<td>27%</td>
<td>15%</td>
</tr>
<tr>
<td>Faecal Incontinence</td>
<td>Vaginal</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>C-Section</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Any pelvic floor disorder</td>
<td>Vaginal</td>
<td>48%</td>
<td>27%</td>
</tr>
<tr>
<td></td>
<td>C-Section</td>
<td>33%</td>
<td>18%</td>
</tr>
</tbody>
</table>

“C-Section reduces your risk of any bothersome/treatment PFD 20 years after delivery by 15%”
UR-CHOICE – More Questions than answers!

Pregnant women

• Views about receiving personalised PFD risk information antenatally and postnatally?
• The likelihood that this information would influence motivation and adherence to PFMT and dietary advice?
• What risk reduction would they wish before considering a Caesar?
UR-CHOICE – More Questions than answers!

Midwives/Obstetricians/Service Managers/Clinical Directors

• Views about delivering personalised PFD risk information antenatally and postnatally?
• What are their views if a woman was higher than average risk?
• What are the implications for services? (Physio, Dietician referrals, ?elective Caesars)
Conclusions of UR-CHOICE “Score”

• Models provide valid individualised risk estimates for the development of PFD 12-20 years after delivery (and the objective effect of Caesar)
• Models are not perfect (C-Stat=1)
• Online risk calculator is available at http://riskcalc.org/UR_CHOICE/
• Predicting risk is major step in prevention
• It supports a woman’s autonomy and her right to informed choice regarding her care in pregnancy and childbirth
• Using UR-CHOICE risk calculator increases awareness of prevention of PFD
“In a century that has witnessed the unravelling of the genetic code, it is surprising how little we know about functional changes in women after vaginal childbirth, how to prevent damage to the pelvic floor and how to treat it”

De Lancey, NEJM 1993
Prevention of Pelvic Floor Dysfunction

- SWEPOP
- PREVPROL
- PROLONG
- UR-CHOICE

- Congenital
- Vaginal birth
- Prolonged 2nd stage
- Forceps
- Constipation
- Ageing
- Muscle avulsion
- Pudendal nerve denervation
- Baby’s Weight
- Oestrogen Deficiency