Pelvic Floor Function and Dysfunction in a General Female Population

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Pelvic Floor Function and Dysfunction in a General Female Population

Functie en Disfunctie van de Bekkenbodem in een Algemene Vrouwelijke Populatie

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de rector magnificus
Prof.dr. H.G. Schmidt
en volgens besluit van het College van Promoties

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Kris Sieradzan

Voor mijn ouders
Voor Jos, Michael en Leontine
Govert en Mariëlle
Remco en Frederike

INHOUD

"De mens vermag niets tegen de wet van de zwaartekracht,
maar de val van water weet hij te benutten."
Elsa Triolet

PART I

INTRODUCTION, AIM AND DESIGN OF THE STUDY AUTHORSHIP AND AFFILIATION

Chapter 1
General introduction and study aims

General introduction

The pelvic floor is a complex of connective tissue, ligaments, fascia and muscle fibres that form a hammock at the bottom of the abdomino-pelvic cavity [1-2]. In women, the function of the pelvic floor is to stabilize the bladder, urethra, bowel and uterus within the pelvis, which is of relevance to urinary and anal continence. Furthermore, the pelvic floor plays an important role during pregnancy and delivery and in sexual functioning.

Pelvic floor dysfunction has been described extensively and is known to cause urinary or faecal incontinence, obstructive micturition or defaecation, pelvic organ prolapse and sexual disorders, such as dyspareunia.[3-12]

Today, pelvic floor dysfunction (PFD) is a hot item and a large number of pelvic floor research centres and clinics in western society are involved in the assessment and treatment of PFD. However, PFD has a long history. As early as in 2000 B.C., there were references to pelvic organ prolapse (POP) and its treatment in the Kahun Papyrus of Egypt. Even Hippocrates (400 A.D.) was of the opinion that wet feet, excessive exertion, fatigue and sexual excesses were the cause of uterine prolapse. A few centuries later, Aetias defined aetiological factors as being a fall, violent extraction of the placenta, a poorly executed delivery, prolonged labour in delivery, excessive heavy lifting or direct injury to the uterus.[13]

Prevalence data on PFD were reported in the International Consultation of Incontinence of 2005: in women, urinary incontinence was present in 5-69% (15-85 years), faecal incontinence (liquid or solid stool incontinence) in 11-15%, POP in 94% and symptoms of POP (such as feeling and/or seeing vaginal bulging) in 7-23% (ICI 2005).[14]

Although symptoms of PFD are common in women and often very bothersome, it seems that only a small percentage of sufferers consult their general practitioner (GP) about these symptoms. However, with the ageing of the population, the number of women who consult their GP about PFD is expected to increase, which will affect the cost of health care. At present, the direct cost of POP surgery already exceeds 1 $ billion per year in the USA.[15]

Therefore, we need to take any measures possible to diminish PFD in women, including POP, to improve their quality of life and decrease the cost of health care. Along these lines, Delancey stated that the high prevalence rates of pelvic floor problems indicate the requirement of preventive strategies and that reaching a goal of 25% prevention would save 90,000 women (in the USA alone) from experiencing PFD.[16] However, the lack of crucial knowledge is standing in the way of effective and optimal measures.

This thesis focus on the prevalence, prediction and risk factors, with emphasis on POP. To be able to develop conservative and hence cheaper interventions for POP, the following steps are necessary: 1) to estimate the need for care in a general female population, 2) to develop effective preventive measures. As conservative treatment, such as pelvic floor muscle physiotherapy, works well with the pelvic floor musculature, we need to gain insight into pelvic floor muscle function in relation to POP.

References

1. Strohbehn K. 1998. Normal pelvic floor anatomy. Obstet Gynecol Clin North Am 25(4):683-705.
2. Keane DP, O'Sullivan S. 2000. Urinary incontinence: anatomy, physiology and pathophysiology. Baillieres Best Pract Res Clin Obstet Gynaecol 14(2):207-226.
3. Hunskaar S, Lose G, Sykes D, Voss S The prevalence of urinary incontinence in women in four European countries. BJU Int 2004 ;93:324-30.
4. Richter HE, Nygaard I, Burgio KL, et al. Lower urinary tract symptoms, quality of life and pelvic organ prolapse: irritative bladder and obstructive voiding symptoms in women planning to undergo abdominal sacrocolpopexy for advanced pelvic organ prolapse. J Urol 2007 178:965-9; discussion 969.
5. Klingele CJ, Carley ME, Hill RF. Patient characteristics that are associated with urodynamically diagnosed detrusor instability and genuine stress incontinence. Am J Obstet Gynecol 2002 186:866-8.
6. Tan TL, Lieu PK, Ding YY Urinary retention in hospitalised older women. Ann Acad Med Singapore 2001 30:588-92.
7. Handa VL, Cundiff G, Chang HH, Helzlouer KJ. Female Sexual Function and Pelvic floor disorders. Obstet Gynecol 2008 111:1045-1052.
8. Rogers GR, Villarreal A, Kammerer-Doak D, Qualls C. Sexual function in women with and without urinary incontinence and/or pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunction 2001 12:361-5.
9. Albers LL, Borders N. Minimizing genital tract trauma and related pain following spontaneous vaginal birth. J Midwifery Womens Health 2007 52:246-53.

10. Swithinbank LV, Donovan JL, Du Heaume JC, et al. Urinary symptoms and incontinence in women: relationships between occurrence, age, and perceived impact. Br J Gen Pract 1999 49:897-900.
11. Burrows LJ, Meyn LA, Walters MD, Weber AM (2004) Pelvic symptoms in women with pelvic organ prolapse. Obstet Gynecol 104:982-8.
12. Batra AK, Mathews R, Lopresti A, Initial experience with the modified vaginal wall sling in the treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1997;8(4):209-12.
13. Emge LA, Durfee RB. 1966. Pelvic organ prolapse: four thousand years of treatment. Clin Obstet Gynecol 9(4):997-1032.
14. Hunskaar S, Burgio K, Clark A, et al. Epidemiology of urinary and faecal incontinence and pelvic organ prolapsed. In: Abrams P, Cardozo L, Khoury S, Wein A, International Continence Society, Sociéte International d'Urology, eds. Incontinence, third annual consultantion on incontinence, 2005, vol 1, Basics and evaluation. Plymouth, England: Health Publications Ltd; 2005:255-312.
15. Subak LL, Waetjen LE, van den Eeden S, Thom DH, Vittinghoff E, Brown JS. 2001. Cost of pelvic organ prolapse surgery in the United States. Obstet Gynecol 98(4):646-651.
16. DeLancey JO. The hidden epidemic of pelvic floor dysfunction: achievable goals for improved prevention and treatment. Am J Obstet Gynecol 2005 192(5):1488-1495.

Study aims

The main research questions were:

1. What is the prevalence of pelvic organ prolapse symptoms in a general female population aged 45-85 years? (Chapter 3)
2. What are the risk factors of pelvic organ prolapse in a general female population, aged 45-85 years? (Chapter 3)
3. What is the prevalence of pelvic organ prolapse, measured by the POPQ, in a general female population, aged 45-85 years? (Chapter 4)
4. Can a questionnaire predict the existence of clinically relevant pelvic organ prolapse in a general female population aged 45-85 years? (Chapter 4)
5. Which bladder and bowel related symptoms of pelvic floor dysfunction are associated with pelvic organ prolapse in a general female population, aged 45-85 years? (Chapter 5)
6. What is the prevalence of urinary incontinence, faecal incontinence and double incontinence in a general female population, aged 45-85 years? (Chapter 6)
7. What is the prevalence of vaginal noise in a general female population, aged 45-85 years? (Chapter 7)
8. How reliable is the pelvic floor muscle assessment scale based on the new terminology of the ICS? (Chapter 8)
9. What is the status of pelvic floor muscle function in a general female population? (Chapter 9)
10. Is there a significant association between muscle strength and endurance of the pelvic floor and other voluntary and involuntary contractions? (Chapter 9)
11. What is the relation between pelvic floor muscle function and pelvic organ prolapse? (Chapter 10)

To address these questions, this study was performed on the general female population in Brielle, aged 45-85 years.

Chapter 2
Study design

Design

A cross-sectional study was performed on a general female population aged 45 to 85 years.

Population

A cross-sectional study was performed on a general female mostly white population aged 45 to 85 years, living in a Dutch town.

The total population of women aged 45-85 years (n=2,979 out of 16,000 citizens) registered on the patient lists of eight out of the nine general practices in the town of Brielle (near Rotterdam, the Netherlands) were approached to participate in the present study. As all the inhabitants are obliged to register with general practitioners, the study population included 95% of the women in this age range. The women were sent information about the study and they could enrol by filling out an informed consent form. They were offered three options: to sign a refusal form, to fill out the questionnaire only or to fill out the questionnaire and undergo vaginal examination.

Flowchart of the study

A flowchart of the study is presented in figure 1. The study consisted of two steps: firstly, the answers to the responder questionnaire were analysed; secondly, the results of the vaginal examination were analysed separately and in combination with the answers to the questionnaire. In addition, a short questionnaire was sent to the non-responders and the answers were analysed. The vaginal examinations were performed in Brielle.

The Medical Ethics Research Committee (METC) of the Erasmus MC in Rotterdam, the Netherlands, approved this study.

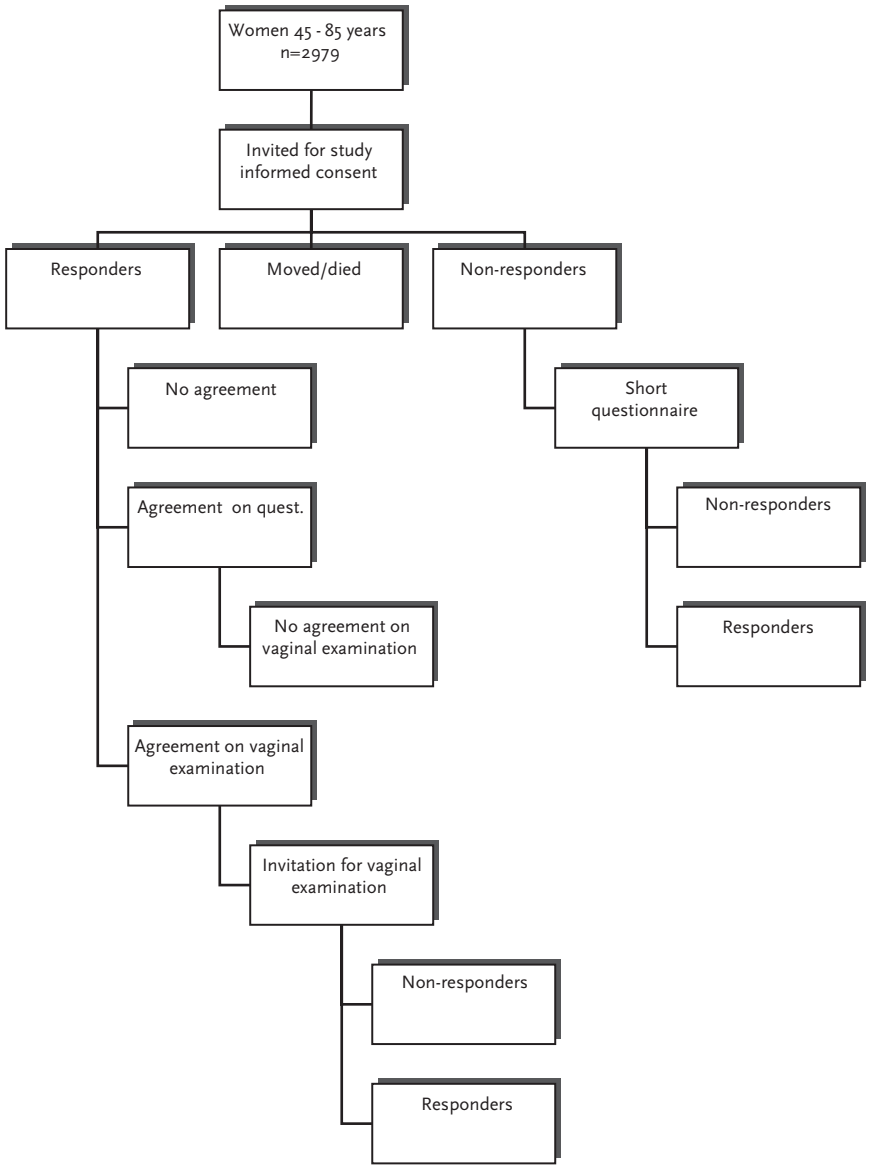


Figure 1 Flowchart of the study

Questionnaire

Validated Dutch pelvic floor questionnaires were used in this study: the Urogenital Distress Inventory [1] and the Defecation Distress Inventory.[2] In addition, subjects were asked about ethnicity, parity, vaginal bulging, incontinence, pelvic girdle pain and vaginal bulging during pregnancy, family history, menopausal status, hormone replacement therapy (HRT), previous pelvic floor surgery, educational level, smoking, heavy physical work in the past or currently. The EuroQol and a VAS scale were used to measure quality of life.[3]

Vaginal examination

Vaginal examination data were obtained with a newly designed Pelvic Floor Muscle (PFM) function assessment and the existing pelvic organ prolapse quantification (POPQ). The POPQ, developed by the ICS [4], and has proven to be valid and reliable.[5] Measurements were carried out in conformity with the ICS standardisation report.

The PFM function assessment was designed on the basis of the International Continence Society (ICS) standardisation report.[6-7] A study was performed to determine its face validity and reliability.

One gynaecologist and one physiotherapist performed the vaginal examinations. Intertester reliability of the PFM assessment was as high as we expected. Therefore a great deal of attention was paid to train the two examiners in the assessment protocol of the vaginal examination until there was close similarity in their testing and registration results. This train took place at the Pelvic Floor Centre at the Erasmus MC in Rotterdam. After each examination, all the details were entered into the scoring form. The two examiners were blinded to the results of the questionnaire. All the women were asked to empty their bladder before the examination.

Non-response study

All the non-responders were asked to fill in a short questionnaire to evaluate whether the responders were representative of the total group. This short questionnaire comprised five questions about age, parity, feeling or seeing vaginal bulging, solid stool incontinence and stress urinary incontinence.

References

1. Van Der Vaart CH, De Leeuw JR, Roovers JP, Heintz Ap (2002) [The influence of urinary incontinence on quality of life of community-dwelling, 45-70 year old Dutch women] De invloed van urine-incontinentie op de kwaliteit van leven bij thuiswonende Nederlandse vrouwen van 45-70 jaar. Ned Tijdschr Geneeskd 144:894-7.
2. Van Brummen HJ, Bruinse HW, Van De Pol G, Heintz AP, Van Der Vaart CH. (2006) Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. Int Urogynecol J Pelvic Floor Dysfunct;17:224-30.
3. Essink-Bot ML and De Haes JCJM. Kwaliteit van leven in medisch onderzoek. Een inleiding. Amsterdam: Amsterdam University Press 1996.
4. Bump, RC, Mattiasson, A, BO, K, Brubaker, LP, Delancey, JO, Klarskov, P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10-7.
5. Swift S (2002) Current opinion on the classification and definition of genital tract prolapse. Curr Opin Obstet Gynecol Oct;14(5):503-7.
6. Messelink B, Benson T, Berghmans B, et al. Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn 2005;24:374-80.
7. Slieker-Ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. 2008a. Face validity and reliability of the first digital assessment scheme of pelvic floor muscle function conform the new standardized terminology of the International Continence Society. Neurourol Urodyn.

Chapter 3
Authorship and affiliations

– **Marijke C.Ph. Slieker-ten Hove**
Department of Obstetrics and Gynecology, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands
Department of Physiotherapy, Erasmus MC, University Medical Centre Rotterdam, The Netherlands
Cobra Research Institute, Amersfoort
SOMT, Master Education in Musculoskeletal therapy

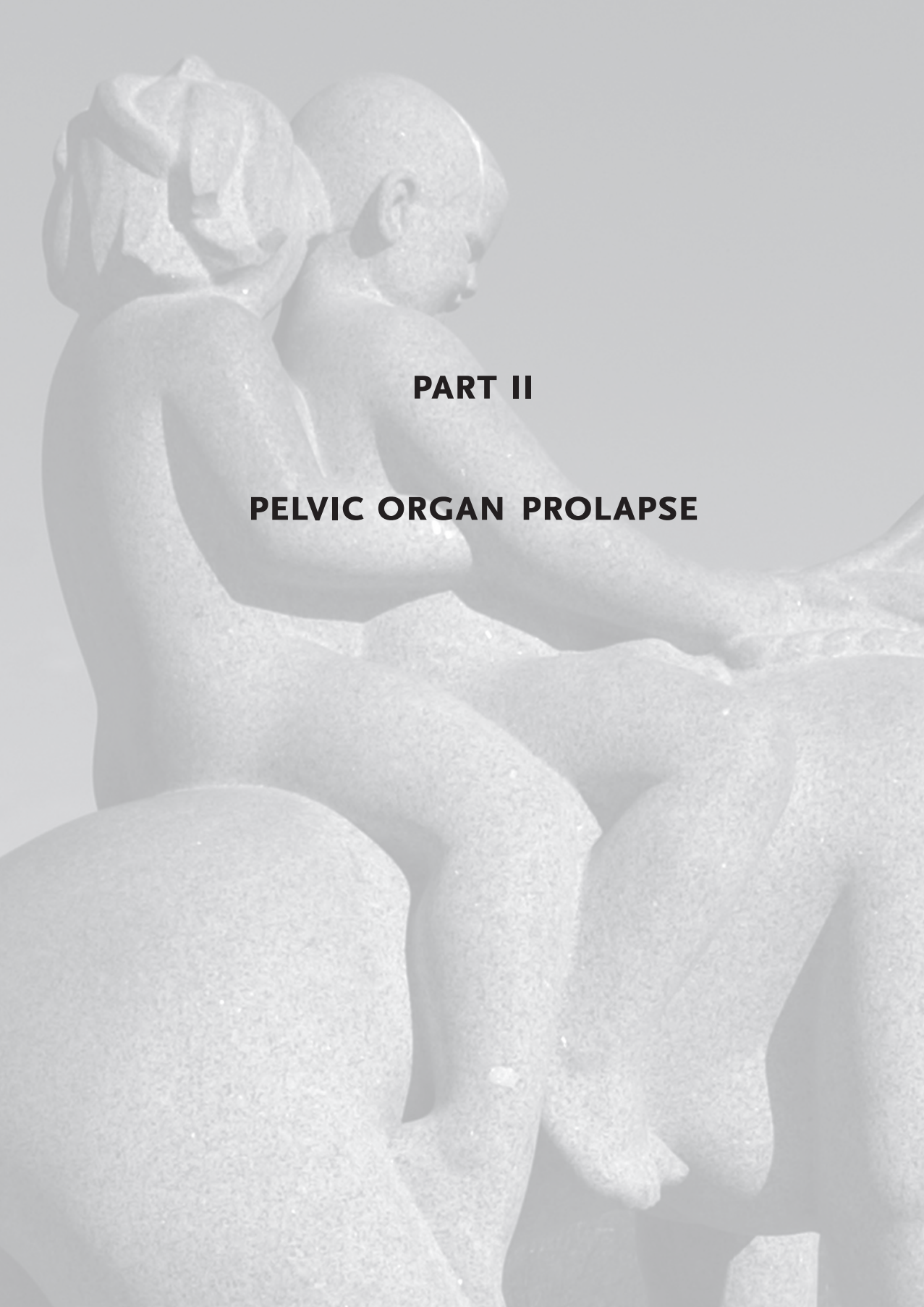
– **Annelies L. Pool-Goudzwaard**
Department of Neuroscience, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands

– **Marinus J.C. Eijkemans**
Department of Public Health, Erasmus MC, University Medical Center, Rotterdam, The Netherlands

– **Regine P.M. Steegers-Theunissen**
Department of Obstetrics and Gynecology, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands
Department of Epidemiology, Erasmus MC, Rotterdam, The Netherlands
Department Pediatrics/Pediatric Cardiology, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands
Department Clinical Genetics, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands

– **Curt W. Burger**
Department of Obstetrics and Gynecology, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands
Division of Gynecological Oncology, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands

– **Mark E. Vierhout**
Department of Obstetrics and Gynaecology, University Medical Centre St. Radboud, Nijmegen, The Netherlands



PART II

PELVIC ORGAN PROLAPSE

Chapter 4

Symptomatic pelvic organ prolapse and possible risk factors in a general population

American Journal of Obstetrics & Gynecology August 29th, 2008

Objective We sought to examine the prevalence of pelvic organ prolapse (POP) symptoms and risk factors in a general white population.
Study Design This was a cross-sectional study. All female residents aged 45-85 years in a small Dutch city received validated questionnaires. Women were classified as symptomatic if they reported feeling and/or seeing vaginal bulge.
Results Response rate was 62.7% (1,869/2,979). Prevalence of POP was 11.4%. Multivariate analysis revealed POP symptoms during pregnancy, a maternal history of POP, and heavy physical work with a total population attributable risk of 46%.
Conclusion There is high prevalence of symptomatic POP in a general white population of which independent risk factors are POP symptoms during pregnancy, a maternal history of POP, and heavy physical work. Clinicians should focus on risk factors in counselling of (pregnant) women to inform women to be aware of further exposures for themselves and their daughters.

Key words pelvic organ prolapse; pelvic organ prolapse quantification; pelvic organ prolapse questionnaire; pelvic organ prolapse risk factor; pelvic organ prolapse symptoms

Introduction

Pelvic organ prolapse (POP) is a condition of descending pelvic organs because of a dysfunction of the tissue support of the pelvic floor.[1] A few studies have been performed on the prevalence of POP in a general population: 1 in Australia,[2] three in Sweden.[3-5] In these studies, using a postal questionnaire, symptomatic POP was found in 4-12.2% of all women. Only a small group seeks medical treatment. In the United States alone, the costs for POP and incontinence surgery are more than $1 billion per year.[6] Increase of costs can be expected because a doubling number of women will seek care in the coming 30 years, as a result of increasing age and changes into a more active lifestyle.[7] In one study, the estimation for the demand for health care services related to pelvic floor disorders will increase at twice the rate of POP itself.[7] To be prepared for the future need of health care of women with POP in the Netherlands, population-based prevalence studies are necessary.

Besides the estimation of the prevalence of symptomatic POP, it is important to identify risk factors to gain insight into the pathophysiology. So far, several risk factors for POP are described. Parity seems to be the strongest risk factor in the development of POP.[3, 8-15] Other reported risk factors are hysterectomy, heavy physical work, education, age, family history, increased chronic abdominal pressure caused by physical work or lung disease, smoking, surgery for urinary incontinence (UI) and/or POP, body mass index (BMI), menopause, hormone replacement therapy (HRT), race, and medication.[16-23] We expect differences in the risk factors reported from other studies compared with the current study because this is a study with no cultural selection bias and was performed in a general population. To examine the prevalence of symptomatic POP in a general population and to identify possible risk factors, we conducted a cross-sectional study with a postal questionnaire survey in a general white population of women aged 45-85 years living in a city in the Netherlands.

Materials and Methods

A cross-sectional study was performed in women, aged 45-85 years. The study design included 2,921 residents of Brielle, a small city near Rotterdam, the Netherlands, with 16,000 citizens. This city was chosen because Rotterdam is multicultural and Brielle is a largely white population. The general practitioners provided hospitality for our research leading to limited travel time for the participating women and a familiar location, which might have been helpful during the examination.

Names and addresses of all 2,921 eligible women aged 45-85 years were obtained from the general practitioners. The study was approved by our medical ethical committee. Women were enrolled via a mailing with information about the POP study and an informed consent form. A flowchart of the study design is presented in Figure 1. All women were asked to complete a set of self-administered questionnaires. A reminder was sent 8 weeks after the first contact. All data were collected anonymously. To avoid selection bias all non-responders were invited to complete a short questionnaire. In this short questionnaire only 5 questions were asked about age, parity, presence of stress UI (yes/no), faecal incontinence (yes/no), and bulge feeling (yes/no). To provide a high response on the questionnaire we used medical institution-identified envelopes, coloured paper, and included stamped return envelopes.[24]

In the POP questionnaires, validated pelvic floor questionnaires such as the Urogenital Distress Inventory[25] (UDI) and the Defecation Distress Inventory (DDI)[26] were used. In addition, information was obtained about ethnicity, parity, POP symptoms and incontinence during pregnancy, family history, menopausal state, HRT, previous pelvic floor surgery, educational level, smoking, and heavy physical work in the past or currently.

Women were classified as symptomatic if they reported positive on feeling and/or seeing vaginal bulge, according to the findings of these questions.[27-28] Differences for the presence of feeling vaginal bulge, stress UI (urine loss ≥ 1/month with at least little bother), and faecal incontinence (loss of fluid or solid stool ≥ 1/month with at least little bother) were tested between non-responders and responders using the outcome on the UDI and DDI.

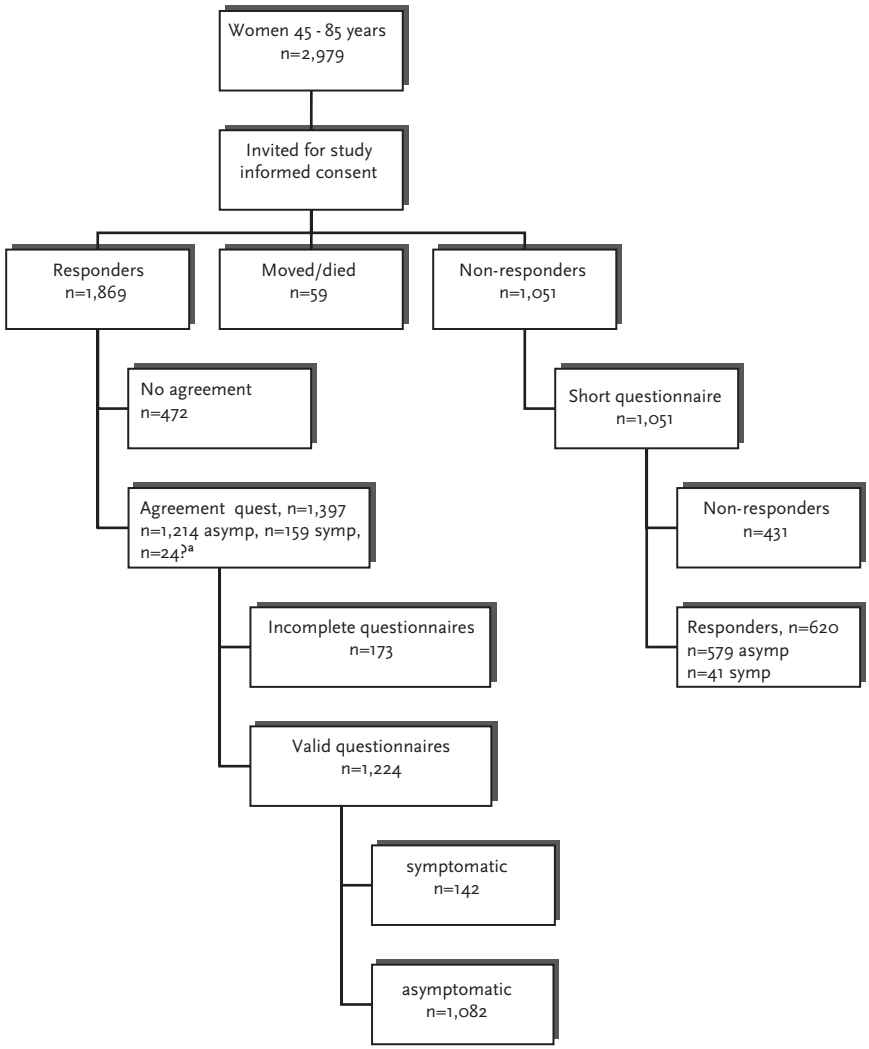


Figure 1 Flowchart of the study

[a] *Because of missing data on vaginal bulging, 24 could not be used.*

Statistical analysis

Summary data are presented as mean ± SD in case of interval type variables and as percentages when categorical. Differences in potential risk factors between the symptomatic and asymptomatic group were tested by Student *t* test and the χ^2 test, respectively, with $P < .05$ as criterion for statistical significance. Univariate and multivariate logistic regression analyses were performed, with

the dichotomized case state as dependent and the covariate variable as the independent variable. In the multivariate analysis, a backward stepwise elimination procedure was applied with $P < .10$ as criterion for removal from the logistic model.[29] The results are expressed as odds ratio (OR) with 95% confidence interval. The population impact of the factors in the final multivariate logistic model on the prevalence of symptoms was assessed by the population attributable risk (PAR) percentage, which is the proportion of symptomatic women in the study population that is attributable to the risk factors in the final multivariate analysis. All analyses were adjusted for age.

Results

The response rate was 62.7% (1,869/2,979). From the non responder group (n = 1,042) another 620 women responded on the short questionnaire. Despite the intimate nature of the questions, only 3% of all questions were not answered. After applying the above-mentioned criteria of feeling and/or seeing bulge, the group could be stratified into an asymptomatic group (n = 1,214) and a symptomatic group (n = 159). In all, 24 women could not be classified in the bulge group because of missing data on this question. In further analysis, 149 were excluded because at least one item in the questionnaire was missing. No default answer categories were provided or could be assumed in case of non-response to specific items in the questionnaire. These questionnaires were, therefore, incomplete.

After exclusion of these incomplete questionnaires, 1,224 women were included with 1,082 asymptomatic women and 142 (11.4%) symptomatic women. In the non-responders group 6.7% (n = 41) was positive on the question of only feeling bulge vs 9.8% (n = 135) in the overall responders group. Thus, a feeling of bulge alone was reported in 8.7% (n = 176) of the total study group plus the short questionnaire non-responders (1,397 + 620 = 2,017).

Baseline characteristics of the total study population and the different groups (overall group questionnaire, overall responders group asymptomatic, and the symptomatic group) are shown in Table 1. No significant differences were shown between the non-responder group and the overall responders group nor could any significance be demonstrated between the asymptomatic and the symptomatic group on parity, stress UI and faecal incontinence ($P < .005$).

Table 1 Baseline characteristics of the total study population divided into symptomatic and asymptomatic groups

Characteristics of study population	Questionnaire total n = 1,397[a]	Total group, control n = 1,214	Total group, symptomatic n = 159 (11.4%)
Mean age, y (range 45-84)	58.0 (SD ± 9.2)	57.8 (SD ± 9.1)	59.0 (SD ± 9.5)
Mean BMI	n = 1,364	n = 1,187	n = 153
	25.6 (SD ± 3.9)	25.6 (SD ± 4.0)	25.5 (SD ± 3.4)
Race	n = 1,372	n = 1,328	n = 156
White	1,351 (96.7)	1,172 (98.5)	156 (99.4)
Nonwhite	20 (1.4)	18 (1.5)	1 (.6)
	n = 1,340	n = 1,165	n = 153
Median parity	2	2	2
0	120 (8.6)	110 (9.1)	9 (5.7)
1	215 (15.4)	184 (15.2)	25 (15.7)
2	675 (48.3)	582 (47.9)	87 (54.7)
≥ 3	387 (27.7)	338 (27.8)	38 (23.9)
Menopausal status	n = 1,383	n = 1,202	n = 159
Menopausal	374 (26.8)	332 (27.6)	39 (24.5)
Postmenopausal	1,009 (72.2)	870 (72.4)	120 (75.5)
Menopause and HRT	n = 1,361	n = 332	n = 38
Menopausal with HRT	24 (1.7)	22 (6.8)	2 (5.3)
Postmenopausal with HRT	63 (4.6)	52 (6.1)	10 (8.3)
Smoking	n = 1,382	n = 1,202	n = 158
Current smoker	280 (20)	248 (20.6)	29 (18.4)
Surgical history	n = 1,384	n = 1,202	n = 159
Prolapse	103 (7.4)	71 (5.9)	29 (18.2)[a] .000
	n = 1,382	n = 1,203	n = 157
Incontinence	47 (3.4)	36 (3.0)	10 (6.4) .032
	n = 1,383	n = 1,202	n = 159
Hysterectomy	234 (16.8)	191 (15.9)	36 (22.6) .024
Family history	n = 985	n = 874	n = 97
Mother POP	359 (25.7)	304 (34.8)	50 (51.5)[a] .001
	n = 870	n = 784	n = 86
Mother UI	258 (29.7)	222 (28.3)	36 (41.9) .008
Educational level	n = 1,374	n = 1,193	n = 158
Primary only	139 (9.9)	117 (9.8)	18 (11.4)
Intermediate	1,039 (75.6)	907 (76)	117 (74.1)
Higher	196 (14.3)	169 (14.2)	23 (14.6)
Heavy physical work	n = 1,381	n = 1,198	n = 159
Current heavy work	269 (19.3)	227 (18.9)	39 (24.5)
	n = 1,384	n = 1,201	n = 159
Ever (past) heavy work	619 (44.3)	531 (44.2)	78 (49.1)

BMI, body mass index; HRT, hormone replacement therapy; POP, pelvic organ prolapse; UI, urinary incontinence. Expressed as numbers (%) and means. [a] Because of missing data, percentages do not always correspond with the whole group. P < .001.

The prevalence of POP symptoms scored no differences by age. The multivariate analysis revealed POP symptoms during pregnancy, a mother with POP and current heavy physical work as independent risk factors. The data of the multivariate analysis are presented in Table 2. Tests on interaction with age on these risk factors and in age groups of 5 and 10 years did not show any significance. Tests on parity were done comparing the nulliparous with the parous group.

Table 2 Odds ratios for feeling/seeing bulge

	Univariate OR (95% CI)	Multivariate[a] OR (95% CI)	PAR, %
Age	1.01 (.99–1.03)	1.017 (1.00–1.04)	—
BMI	.99 (.95–1.03)		
Parous vs nulliparous	1.76 (.84–3.68)		
Postmenopausal	1.17 (.80–1.72)		
HRT	1.22 (.65–2.29)		
Smoking	.87 (.57–1.33)		
Hysterectomy	1.55 (1.04–2.32)[a]		
Incontinence surgery	2.21 (1.07–4.54)[a]		
High vs low education	.85 (.50–1.43)		
Current heavy physical work	1.39 (.94–2.05)	1.48 (.98–2.23)	8.5
Past heavy physical work	1.22 (.87–1.69)		
Incontinence during pregnancy	1.48 (1.03–2.12)		
POP symptoms during pregnancy	2.29 (1.59–3.29)	2.06 (1.42–3.00)	17.8
Mother prolapse	1.99 (1.31–3.04)[a]	1.67 (1.10–2.54)	19.7
Mother incontinence	1.82 (1.16–2.88)[a]		

BMI, body mass index; CI, confidence interval; HRT, hormone replacement therapy; OR, odds ratio; PAR, population attributable risk; POP, pelvic organ prolapse.Univariate and multivariate analysis of the risk factors ([a] selected with P < .10).

Comment

The most important findings in this study were the high prevalence of more than 11% of women reporting POP symptoms with risk factors of POP symptoms during pregnancy, a mother with POP and current heavy physical work. This resulted in a PAR of 46% indicating that 46% of all POP can be explained by the above-mentioned risk factors. For women, this is crucial information. Although only heavy lifting is modifiable, the combination with hereditary components and bulge symptoms during gestation are able to take into account that heavy lifting contributes to development of POP. In our study we defined the presence of POP by a positive answer on the question: "Do you see or feel a vaginal bulge?" This assumption is based on the findings of Tan et al[28] demonstrating the predictive value of this question (81%) for POP.

Strengths and limitations

We defined symptoms of POP as feeling and/or seeing a vaginal bulge. Other possible symptoms like urinary splinting or rectal bulging were not considered to be specific. This choice was supported by the recent International Consultation on Incontinence report.[30] In a recent article, similar questions of vaginal bulging were found to have a high specificity and sensitivity for the presence of POP.[27]

The response rate on our questionnaire was 62.7% and, excluding all negative responding women, this rate decreased to 51%. However, the non-responder group confirmed largely the representation of the population. We tried to increase the response with a second request supported with different colours of envelopes. An announcement in the local newspaper was published in that same week and full support of the general practitioners in Brielle, the Netherlands, was available. Fortunately, the response on the non-responder questionnaire was almost 59% and supported largely the cross section of the study group and the differences were not significant.

The study group was almost completely white, which is not representative for the multiracial character of the Dutch population. Nevertheless, because POP has different prevalence's coupled with ethnicity,[31] the mono ethnicity in the current study will enlarge the understanding of POP and risk factors in a white population.

POP symptoms

As mentioned above, in this cross-sectional study among women aged 45-85 years, more than 11% of women reported POP symptoms of seeing and/or feeling bulge. The earlier-mentioned Australian cross-sectional study[2] (n = 1,546) reported a prevalence of POP of 8.8%, but this was only based on the question of feeling a vaginal bulge. This is comparable with our data of 9.7% for only feeling a vaginal bulge. Our data conflict with the study of Eva et al.[32] (n = 2,000), also performed in Sweden, where only 4% reported genital bulge symptoms. The study of Eva et al.[32] in Sweden studied 2 cohorts, 1 with 40-year-old women and 1 with 60-year-old women. Differences in the prevalence of POP can be the definition of POP itself. An explanation can be that from this Swedish study it is not clear whether the question of seeing or feeling bulge was defined. Eva et al. did not describe which question was used to discriminate between genital bulge or not.[32] Only genital bulge is mentioned. So, a different question can lead to different prevalence scores.

Another cross-sectional study on a Swedish general population of Samuelsson et al.[4] (n = 641) reported a prevalence of POP of 30.8%. However, in this study the question to define POP in women was: "Do you feel a sense of heaviness in the lower abdomen?" The predictive value (specificity) of this question as reported by Tan et al.[28] is not as high as the question we used in the current study. This may explain the differences in POP prevalence between our study and the study of Samuelsson et al.[4] Furthermore the number of subjects is smaller than in our study.

In contrast with our mono-racial study, Rortveit et al.[33] (n = 2,001) reported a prevalence of 6% in a multiracial population. This supports the hypothesis that there is a possible ethnic difference as a proxy of genetic background and lifestyles in developing POP, also confirmed by other studies.[31, 34-35]

Risk factors

Many independent risk factors have been observed for the prevalence of POP. Bump and Norton [34] divided risk factors into predisposal, decompensating, inciting, and promoting factors. We will follow this order.

The most important predisposed risk factor of our study, using multivariate analysis, was the history of POP in the mother with an OR of 1.67. We must be careful to interpret this result because of a possible bias because older women in this cohort might have problems remembering the presence of POP in their mothers. However, the above mentioned results are in line with 3 recent studies of Jack et al.[21], Chiaffarino et al.[36], and Altman et al.[23] who demonstrated a familial inheritance pattern of POP with a high degree of penetrance in families.

For the decompensating risk factor, age could not be demonstrated in the current study. This result is comparable with the studies of Swift[37], Hendrix et al.[12], Progetto Menopausa Italia Study Group [38] and Mant et al.[39] Comparison of the results is difficult because of differences in reported perimenopausal periods and the multiple regimens of hormone use.

The inciting risk factor parity is often mentioned as the strongest risk factor in the development of POP.[3, 8-15] Our study demonstrated that the mother with POP has a higher risk factor. Especially on POP symptoms during gestation, we demonstrated an OR of 2.06 in the multivariate analysis with a PAR of 17.8%. As far as we know, this is the first time that POP symptoms during pregnancy are identified as risk factor and responsible for high PAR. Hysterectomy and incontinence surgery are reported to be inciting risk fac-

tors as well.[3,12,14,39] However, we could not demonstrate this in our study. Furthermore, different methods of analysis are used.

Finally, in the promoting risk factors, current heavy physical work demonstrated in multivariate analysis an OR of 1.48. The risk factor of heavy physical work is also reported by Woodman et al.[18] The results of our study are in line with their findings. BMI as a possible risk factor could not be demonstrated in the current study. This is in line with the findings of Nygaard et al.[13], although in contrast with the findings of Hendrix et al.[12] and Swift et al.[15]. These differences can be explained by the relatively low mean BMI in our symptomatic group of 25.5.

Because of the expected increase of health care in women with POP it is important to study possibilities to prevent POP. Until now, parity and aging were described as the most important risk factors of POP,[3,8-15] indicating that prevention of POP seems impossible. Our results are partly in line with these studies. We demonstrated that a mother with POP, POP symptoms during gestation, and heavy physical work are important risk factors as well, of which heavy physical work is modifiable. Nevertheless, the question arises of how to detect women in an early state and how to create secondary preventive strategies. Different studies suggest that women are not aware of any form of POP as long as it does not reach the hymen.[16,18,37] For that reason, women first learn about POP when they become symptomatic and they only require and receive information that, especially surgical treatment, is available when and if their symptoms become bothersome.[16] A policy of carefully waiting is then promoted.

However, combining the 3 demonstrated most important risk factors, which cover a PAR of 46%, opens new doors in the development of (secondary) preventive strategies. Now it is possible to detect women at high risk for POP already during gestation. Gynaecologists, obstetricians, midwives, and physiotherapists should ask questions to pregnant women about POP and inform them about the risk factors. After all, during pregnancy, which mostly is in an early phase of life, women become aware of their pelvic floor during prenatal and postnatal classes. Although they will not be able to reduce the exposure to risk factors such as maternal history and POP symptoms during pregnancy, women should learn in this early period in life to be aware that heavy lifting might increase POP. This is crucial information especially for those women with high risk because of a mother with POP and POP symptoms during gestation. In this way women can adapt their daily activities to adjust heavy lifting tasks.

Maybe pelvic floor muscle training is effective to decrease the risk on POP symptoms. More research needs to be done to study the pelvic floor muscle function in pregnant women and in women with POP symptoms to be able to

develop (secondary) preventive and intervention strategies, which would help to decrease health care cost of POP in future.[7,40-41]

Based on the findings of this study we recommend that clinicians incorporate questions about the demonstrated risk factors in the subjective assessment as POP symptoms during pregnancy, a maternal history of POP, and current heavy physical work. Additional information can be given both to the gravida and to women to inform their daughters to be aware of the exposure to risk factors such as obesity, smoking, and heavy physical work. Studies with physical examination are needed to study the relationship between POP symptoms and signs. Furthermore, randomized clinical trials need to be performed to study the effect of (secondary preventive) different conservative intervention strategies such as physiotherapy and lifestyle interventions, especially on the group of young women who are dealing with all 3 abovementioned risk factors.

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References

1. R.C. Bump, A. Mattiasson and K. Bo *et al.*, The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction, *Am J Obstet Gynecol* **175** (1996), pp. 10–17
2. A.H. Maclennan, A.W. Taylor, D.H. Wilson and D. Wilson, The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery, *BJOG* **107** (2000), pp. 1460–1470.
3. G. Tegerstedt, M. Maehle-Schmidt, O. Nyren and M. Hammarstrom, Prevalence of symptomatic pelvic organ prolapse in a Swedish population, *Int Urogynecol J Pelvic Floor Dysfunct* **16** (2005), pp. 497–503.
4. E.C. Samuelsson, F.T. Victor, G. Tibblin and K.F. Svardsudd, Signs of genital prolapse in a Swedish population of women 20 to 59 years of age and possible related factors, *Am J Obstet Gynecol* **180** (1999), pp. 299–305.
5. E. Uustal Fornell, G. Wingren and P. Kjolhede, Factors associated with pelvic floor dysfunction with emphasis on urinary and fecal incontinence and genital prolapse: an epidemiological study, *Acta Obstet Gynecol Scand* **83** (2004), pp. 383–389.
6. A.L. Olsen, V.J. Smith, J.O. Bergstrom, J.C. Colling and A.L. Clark, Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence, *Obstet Gynecol* **89** (1997), pp. 501–506.

7. K.M. Luber, S. Boero and J.Y. Choe, The demographics of pelvic floor disorders: current observations and future projections, *Am J Obstet Gynecol* **184** (2001), pp. 1496–1503.
8. S.H. Boyles, A.M. Weber and L. Meyn, Procedures for pelvic organ prolapse in the United States, 1979-1997, *Am J Obstet Gynecol* **188** (2003), pp. 108–115.
9. J.T. Wei and J.O. De Lancey, Functional anatomy of the pelvic floor and lower urinary tract, *Clin Obstet Gynecol* **47** (2004), pp. 3–17.
10. C. Dannecker and C. Anthuber, The effects of childbirth on the pelvic-floor, *J Perinat Med* **28** (2000), pp. 175–184.
11. E.J. Gill and W.G. Hurt, Pathophysiology of pelvic organ prolapse, *Obstet Gynecol Clin North Am* **25** (1998), pp. 757–769.
12. S.L. Hendrix, A. Clark, I. Nygaard, A. Aragaki, V. Barnabei and A. Mctiernan, Pelvic organ prolapse in the women's health initiative: gravity and gravidity, *Am J Obstet Gynecol* **186** (2002), pp. 1160–1166.
13. I. Nygaard, C. Bradley and D. Brandt, Pelvic organ prolapse in older women: prevalence and risk factors, *Obstet Gynecol* **104** (2004), pp. 489–497.
14. S.R. Swift, T. Pound and J.K. Dias, Case-control study of etiologic factors in the development of severe pelvic organ prolapse, *Int Urogynecol J Pelvic Floor Dysfunct* **12** (2001), pp. 187–192.
15. S. Swift, P. Woodman and A. O'Boyle *et al.*, Pelvic organ support study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects, *Am J Obstet Gynecol* **192** (2005), pp. 795–806.
16. A.M. Weber and H.E. Richter, Pelvic organ prolapse, *Obstet Gynecol* **106** (2005), pp. 615–634.
17. Q. Chou, A.M. Weber and M.R. Piedmonte, Clinical presentation of enterocele, *Obstet Gynecol* **96** (2000), pp. 599–603.
18. P.J. Woodman, S.E. Swift and A.L. O'Boyle *et al.*, Prevalence of severe pelvic organ prolapse in relation to job description and socioeconomic status: a multicenter cross-sectional study, *Int Urogynecol J Pelvic Floor Dysfunct* **17** (2006), pp. 340–345.
19. H. Gurel and S.A. Gurel, Pelvic relaxation and associated risk factors: the results of logistic regression analysis, *Acta Obstet Gynecol Scand* **78** (1999), pp. 290–293.
20. C.S. Bradley, M.B. Zimmerman, Y. Qi and I.E. Nygaard, Natural history of pelvic organ prolapse in postmenopausal women, *Obstet Gynecol* **109** (2007), pp. 848–854.
21. G.S. Jack, G. Nikolova, E. Vilain, S. Raz and L.V. Rodriguez, Familial transmission of genitovaginal prolapse, *Int Urogynecol J Pelvic Floor Dysfunct* **17** (2006), pp. 498–501.
22. G.M. Buchsbaum, E.E. Duecy, L.A. Kerr, L.S. Huang and D.S. Guzick, Urinary incontinence in nulliparous women and their parous sisters, *Obstet Gynecol* **106** (2005), pp. 1253–1258.
23. D. Altman, M. Forsman, C. Falconwer and P. Lichtenstein, Genetic influence on stress urinary incontinence and pelvic organ prolapse, *Eur Urol* **54** (2008), pp. 918–922.
24. P. Edwards, I. Roberts and M. Clarke *et al.*, Increasing response rates to postal questionnaires: systematic review, *BMJ* **324** (2002), p. 1183.

25. C.H. Van Der Vaart, J.R. De Leeuw, J.P. Roovers and A.P. Heintz, De invloed van urine-incontinentie op de kwaliteit van leven bij thuiswonende Nederlandse vrouwen van 45-70 jaar [The influence of urinary incontinence on quality of life of community-dwelling, 45-70 year old Dutch women], *Ned Tijdschr Geneeskd* **144** (2000), pp. 894–897.
26. H.J. Van Brummen, H.W. Bruinse, G. Van De Pol, A.P. Heintz and C.H. Van Der Vaart, Defecatory symptoms during and after the first pregnancy: prevalences and associated factors, *Int Urogynecol J Pelvic Floor Dysfunct* **17** (2006), pp. 224–230.
27. M.D. Barber, N.L. Neubauer and V. Klein-Olarte, Can we screen for pelvic organ prolapse without a physical examination in epidemiologic studies?, *Am J Obstet Gynecol* **195** (2006), pp. 942–948.
28. J.S. Tan, E.S. Lukacz, S.A. Menefee, C.R. Powell and C.W. Nager, Predictive value of prolapse symptoms: a large database study, *Int Urogynecol J Pelvic Floor Dysfunct* **16** (2005), pp. 203–209.
29. E.W. Steyerberg, M.J. Egkemans, F.E. Harrel and J.D. Habbema, Prognostic modeling with logistic regression analysis: a comparison of selection and estimation methods in small data sets, *Stat Med* **19** (2000), pp. 1059–1079.
30. Hunskaar S, Burgio K, Clark A, et al. Epidemiology of urinary and faecal incontinence and pelvic organ prolapsed. In: Abrams P, Cardozo L, Khoury S, Wein A, International Continence Society, Sociéte International d'Urology, eds. Incontinence, third annual consultantion on incontinence, 2005, vol 1, Basics and evaluation. Plymouth, England: Health Publications Ltd; 2005:255-312.
31. L. Hoyte, J. Thomas, R.T. Foster, S. Shott, M. Jakab and A.C. Weidner, Racial differences in pelvic morphology among asymptomatic nulliparous women as seen on three-dimensional magnetic resonance images, *Am J Obstet Gynecol* **193** (2005), pp. 2035–2040.
32. U.F. Eva, W. Gun and K. Preben, Prevalence of urinary and fecal incontinence and symptoms of genital prolapse in women, *Acta Obstet Gynecol Scand* **82** (2003), pp. 280–286.
33. G. Rortveit, Y.S. Hannestad, A.K. Daltveit and S. Hunskaar, Age- and type-dependent effects of parity on urinary incontinence: the Norwegian EPINCONT study, *Obstet Gynecol* **98** (2001), pp. 1004–1010.
34. R.C. Bump and P.A. Norton, Epidemiology and natural history of pelvic floor dysfunction, *Obstet Gynecol Clin North Am* **25** (1998), pp. 723–746.
35. W.J. Brown and Y.D. Miller, Too wet to exercise? Leaking urine as a barrier to physical activity in women, *J Sci Med Sport* **4** (2001), pp. 373–378
36. F. Chicffanno, L. Chalenand, M. Dindelli, M. Meschic, A. Buonaguidi and F. Amicarelli *et al*., Reproductive factors, family history, occupation and risk of urogenital prolapse, *Eur J Obstet Gynecol Reprod Biol* **82** (1999), pp. 63–67.
37. S.E. Swift, The distribution of pelvic organ support in a population of female subjects seen for routine gynecologic health care, *Am J Obstet Gynecol* **183** (2000), pp. 277–285.
38. Progetto Menopausa Italia Study Group, Risk factors for genital prolapse in nonhysterectomized women around menopause: results from a large cross-sectional study in menopausal clinics in Italy, *Eur J Obstet Gynecol Reprod Biol* **93** (2000), pp. 135–140.

39. J. Mant, R. Painter and M. Vessey, Epidemiology of genital prolapse: observations from the Oxford Family Planning Association study, *Br J Obstet Gynaecol* **104** (1997), pp. 579–585.
40. J.O. DeLancey, The hidden epidemic of pelvic floor dysfunction: achievable goals for improved prevention and treatment, *Am J Obstet Gynecol* **192** (2005), pp. 1488–1495.
41. H.P. Drutz and M. Alarab, Pelvic organ prolapse: demographics and future growth prospects, *Int Urogynecol J* **17** (2006), pp. S6–S9.

Chapter 5

Prediction model and prognostic index on pelvic organ prolapse in a general population

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Abstract

Introduction Estimation on prevalence and distribution of pelvic organ prolapse (POP) signs in a general female population is difficult. We therefore developed and validated a prediction model and prognostic instrument.
Methods Questionnaires were sent to a general female population (45-85 years). A random sample underwent vaginal examination for POP (POPQ). A prediction model was developed using multivariate analysis and validated in a subgroup of participants.
Results Positive questionnaire-response-rate was 46.8% (1,397/2,979). From the questionnaire group 649 women were vaginally examined (46.5%). Prevalence of clinically relevant POP was 21%. Multivariate analysis demonstrated significantly higher odds ratios on the report of vaginal bulging, parity ≥ 2 and a mother with POP. The Receiver Operating Characteristic Curve (ROC) showed Areas Under the curve (AUC) of .672 and .640.
Conclusion The prevalence of clinically relevant POP could be estimated in a general female population using our prediction model with 17 questions and our POP score chart with eight questions.

Keywords pelvic organ prolapse, POPQ, prediction model, prevalence, vaginal bulging.

Summary

Clinically relevant POP in a general population was 21%. Our prediction model and POP score chart can estimate prevalence's of clinically relevant POP without vaginal examination.

Introduction

Pelvic organ prolapse (POP) is part of a range of conditions that are related to pelvic floor dysfunction such as urinary incontinence, bowel disorders and the report of vaginal bulging.[1,2] The lifetime prevalence in women of over 50 years of age is 30-50%.[3] Women have an 11-11.8% chance of undergoing at least one surgical intervention for POP or incontinence by the age of 79 years, with a re-operation rate of 29.2%.[4,5] Complication rates after surgery in different racial groups were reported to be 19.4% (white), 34.1% (black) and 27.4% (other).[6] POP is therefore associated with a high financial burden on health care.[4] Although only a relatively small number of women with POP seek treatment it is expected that this number will increase in the future.[7] At present, the direct cost of POP surgery already exceeds 1 $ billion per year in the United States alone.[8]

To estimate the care requirements of women with POP in the future, it is important to have reliable prevalence data from a general female population. Data must be obtained using a questionnaire and vaginal examination, because there is only a moderate correlation between the signs of POP (measured by vaginal examination) and the symptoms (measured by a questionnaire).[9,10]

To obtain reference data on the prevalence and distribution of POP-signs and the POP-symptom of feeling and/or seeing a vaginal bulge, we conducted a cross-sectional study on a general population of women aged 45-85 years. Our first aim was to develop and validate a prediction model that will be helpful to researchers and health care policy makers. We focussed on three different cut-off points, because of a discrepancy between feeling and/or seeing a vaginal bulge (the cornerstone symptom of POP) and the presence of POP signs in literature. A high correlation between signs and symptoms can be present when a different cut-off point is taken regarding the presence of POP. Therefore we looked at 1 cm above, at the hymen and 1 cm beyond the hymen. Secondly, we created a POP score chart and a prognostic index to estimate the presence of POP in a general population without vaginal examination and the amount of care needed by women.

Material and Methods

A cross-sectional study was performed on a general population of women aged 45 to 85 years. A flowchart of the study design is presented in figure 1. The study population comprised 2,979 women, registered in the office records of eight out of nine general practitioners in Brielle. Brielle is a town near Rotterdam (the Netherlands) with 16,000 citizens. Because all inhabit-

ants have the obligation to be registered in a general practitioners clinic, the study population contained 95% of all women in Brielle. It has an almost exclusively white population (98.4%). Names and addresses of all 2,979 eligible women aged 45-85 years were obtained from the general practitioners. The women were sent information about the pelvic floor study and could be enrolled by filling out an informed consent form. They were offered three options: to sign a refusal form, or to fill out the questionnaire only, or to fill out the questionnaire and undergo vaginal examination.

All the women were asked to complete a self-report questionnaire. A reminder, containing the same questionnaire, was sent eight weeks after the first contact. The data were collected anonymously. To avoid selection bias, non-responders were invited to complete a short questionnaire that comprised five questions about: age, parity, presence of stress urinary incontinence (yes/no), faecal incontinence (yes/no) and feeling of vaginal bulging (yes/no). To encourage a high response to the questionnaire, we used envelopes with the name and logo of the Erasmus University, coloured paper and stamped-addressed-return envelopes.[11]

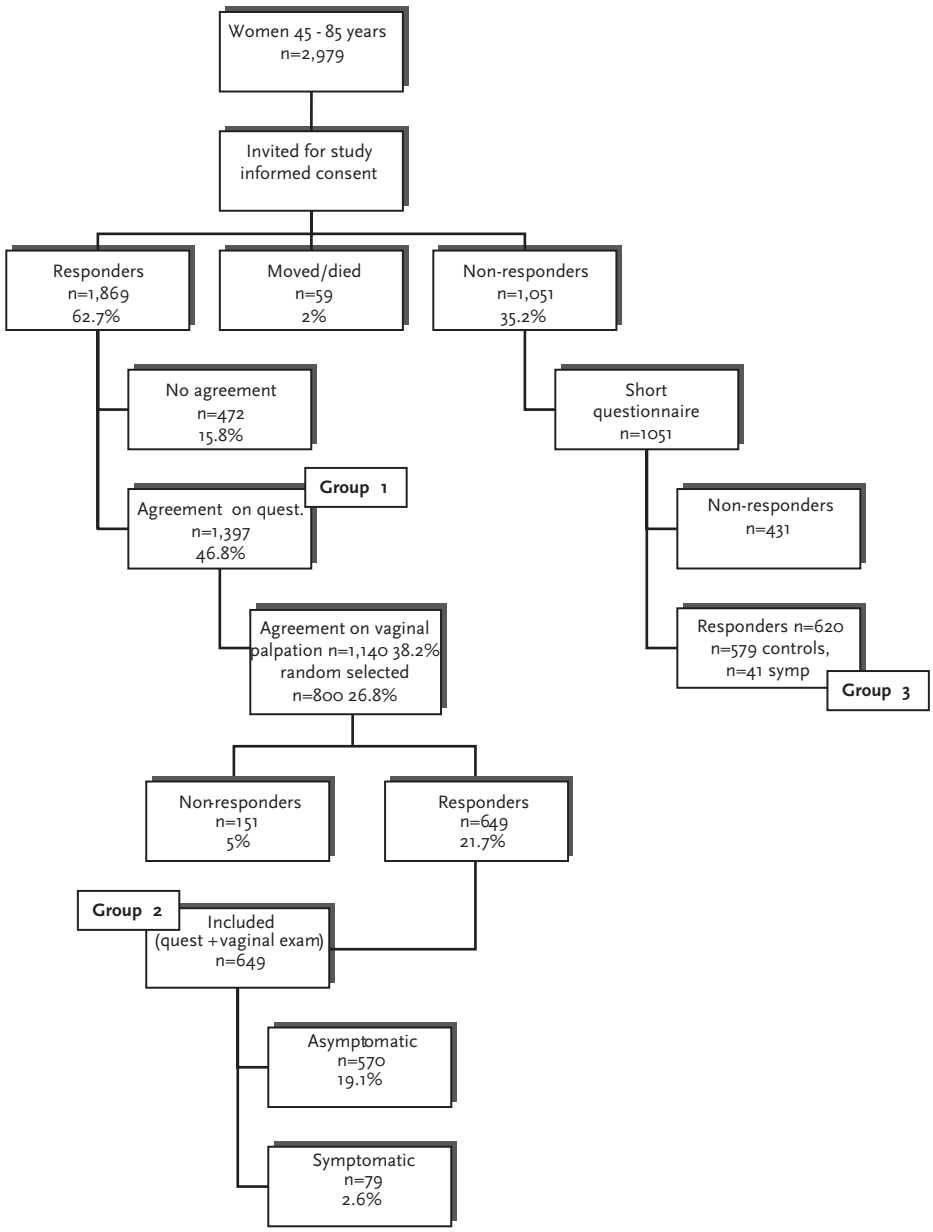


Figure 1 Flowchart of the study

The questionnaire used in this study combined several Dutch validated pelvic floor questionnaires, such as the Urogenital Distress Inventory (UDI)[12] and the Defaecation Distress Inventory (DDI).[13] In addition, subjects were asked about ethnicity, parity, vaginal bulging, incontinence, pelvic girdle pain and vaginal bulging during pregnancy, family history, menopausal status, hormone replacement therapy (HRT), previous pelvic floor surgery, educational level, smoking, heavy physical work at present or in the past.

Vaginal examination

From all the participants who gave informed consent in the beginning of the study to undergo vaginal examination (n=1,140), eight hundred women were randomly selected by age for POPQ measurement. (All respond forms of the women were registered with a number that identified the age and they were at random taken by a research assistant). The POPQ was introduced by the International Continence Society (ICS). It has become widely accepted and proven to be valid [1] and reliable.[14]

A gynaecologist (MV) and a physiotherapist (MS) performed the vaginal examinations. The two examiners practiced the POPQ measurement protocol until they reached agreement about the test and registration scores. This process was performed at the Pelvic Floor Centre at the Erasmus MC in Rotterdam. POPQ measurements were carried out in conformity with the ICS standardisation report [1]. After each examination, all the details were entered into the three-by-three POPQ grid. The two examiners were blinded to the results of the questionnaire. The women were asked to empty their bladder before the examination.

Women were assigned to one of five ordinal stages of prolapse (0 – 4) in accordance with the POPQ grading system. All the methods, definitions and descriptions were in line with the ICS.[1]

To make a detailed analysis of stage 2, we divided it into 2A (indicating 1 cm above the hymen), 2B (0) and 2C (1 cm beyond the hymen). So, for example the cut-off point 2A means that all subjects with POP stage 2A till stage 4 are used for analyses. Within the vaginal examination group, the women were classified into the symptomatic group if they reported feeling and/or seeing vaginal bulging, all others were included in the asymptomatic group.

Statistical analysis

Logistic regression was used to develop multivariate prediction models on the risk of prolapse. Three different definitions of prolapse were used and compared, based on the three cut-off points on the POPQ scale 2A, 2B and

2C. Backwards elimination of the predictors was used. Variables with $P < .3$ were kept in the model. This strategy eliminates most of the purely random variables and improves the chance that the model will perform well in future patients.[15] The predictive performance of the three resulting models was transformed into ROC curves and the areas under the curves (AUC) were compared. There was a limited number of missing values on many of the variables. As multivariate analysis is severely hampered by missing values and more importantly, results may be biased, we used multiple imputation with 10 datasets.[16]

Internal validation of the models was performed by a bootstrap re-sampling procedure: the model building process was repeated 200 times after creating 200 new datasets (bootstrap samples) by randomly drawing cases (with replacement) from the original data. The variable selection and estimation procedure was performed on each bootstrap sample. This yielded 200 sets of predictors and parameter estimates. The model estimates of each bootstrap sample were evaluated on the basis of the original data. On average, the predicted and observed outcomes should agree. Predictions that deviate strongly from the mean usually differ greatly from the observed outcomes due to over-fitting of the model. The size of the over- fitting-effect was estimated by averaging the 200 bootstrap samples. This produced a shrinkage factor c to compensate for the over-fitting.[17] The bootstrap method was also used to estimate the amount of optimism in the AUC, by optimally fine-tuning a model and subsequently evaluating its predictive performance on the same data.[17]

The prediction model that showed the highest AUC was translated into a pragmatic prognostic score, the Slieker-POP-Score. For each prognostic factor in the model, the regression coefficients in the logistic model were converted into score points. For ease of use, the regression coefficients were scaled and rounded to whole numbers, such that the minimum and maximum score of women in our data set were 0 and 100 respectively. From a graph, the corresponding risk of POP can be read off.

The analyses were performed using the Statistical Package for Social Science (SPSS Inc) 15.0. The Medical Ethics Research Committee (METC) of the Erasmus MC in Rotterdam, the Netherlands, approved this study.

Results

Response rate

The response rate to the questionnaire was 62.7% (1,869/2,979). In the group of 1,869 responders, 472 women refused to participate, 1,397 (group 1) women agreed to fill out the large questionnaire and 1,140 agreed to fill out the large questionnaire and undergo vaginal examination. In the non-responder group 3, 59% returned the completed short questionnaire (620/1,051) Feeling vaginal bulging was reported by 6.7% (n=41) of this non-responder group versus 9.8% in the responder group (135/1,397). Eight hundred out of the 1,140 women who consented to undergo vaginal examination were selected at random and sent an invitation for vaginal examination: 649 women (group 2) participated (81.1%), which was 46.4% of the total study population. The vaginal examination group of 649 women was stratified into an asymptomatic control group (n=570) and a symptomatic (n=79) group in which the women had reported seeing and/or feeling vaginal bulging. Combining the data on the large and short questionnaires from the responders and the initial non-responders (1,397+620 = 2,017) revealed a feeling of vaginal bulging prevalence rate of 8.7% (n=176).

Table I **Baseline characteristics of the total study population Group 1, Group 2 who underwent vaginal examination divided into symptomatic and asymptomatic women expressed as percentages (%) with means and the non-responders who filled out the short-questionnaire Group 3**

	Questionnaire 1 Group 1 n=1,397	Vaginal exam Group 2 n=649		Short Questionnaire
Characteristics of the study population		**no bulge n=570**	**bulge n=79 (12.2%)**	**non-responders Group 3 n=620**
Mean age (range 45-84) yrs	58.0 (SD ± 9.2)	58.0 (SD ± 8.9)	59.3 (SD ± 9,1)	**59.2**
Mean BMI	25.6 (SD ± 3.9)	25.6 (SD± 3.7)	25.5 (SD± 3.1)	
Ethnicity				
White	1,351 (98.4)	545 (98.7)	78 (100)	
Non-white	20 (1.5)	7 (1.3)	0	
Educational level	n=1,374	n=556	n=78	
Primary only	139 (9.9)	63 (11.3)	7 (9)	
Intermediate	1,039 (75.6)	420 (75.5)	60 (76.9)	
Higher	196 (14.3)	73(13.1)	11 (14.1)	
	n=1,340	n=551	n=78	
parity, median	2	2	2	2
0	120 (8.9)	46 (8.3)	3 (3.8)	67 (10.6)
1	215 (16)	71 (12.9)	13 (16.6)	102 (16.1)
2	675 (50.3)	273 (49.5)	46 (58.9)	277 (43.6)
≥3	387 (28.8)	161 (29.2)	16 (20.5)	180 (28.3)
Menopausal status	n=1,383	n=557	n=79	
(Pre)menopausal	374 (27)	151 (27.1)	16 (20.2)	
Postmenopausal	1,009 (72.9)	406 (72.9)	63 (79.7)	
(Pre/post)menopausal with HRT	n=1,361	n=551	n=79	
(Pre)menopausal with HRT	24 (1.7)	9 (1.6)	0	
Postmenopausal with HRT	63 (4.6)	23 (4.2)	7 (8.9)	
Smoking	n=1,382	n=556	n=78	
Current Smoker	280 (20.2)	117 (21)	16 (20.5)	
Ever Smoker	345 (46.3)	158 (54.8)	25 (64.1)	
Incont in pregnancy	342 (25.8)	141 (30.7)	23 (26)	
	n=1,328	n=541	n=75	
POP in pregnancy	270 (20.3)	113 (20.9)	28 (37.3)	
Surgical history	n=1,384	n=557	n=79	
Prolapse	103 (7.4)	37 (6.6)	16 (20.2)	
Incontinence	47 (3.4)	21 (3.8)	3 (3.9)	
Hysterectomy	234 (16.9)	85 (15.3)	20 (25.3)	
Family history	n=985	n=397	n=44	
Mother POP	359 (26.4)	139 (35)	22 (50)	
	n=870	n=357	n=41	
Mother UI	258 (29.6)	106 (29.7)	16 (39)	
Heavy physical work	n=1,381	n=553	n=79	
Currently	269 (19.3)	109 (19.7)	18 (22.8)	
	n=1,384	n=556	n=79	
Ever	619 (44.3)	248 (44.6)	39 (49.3)	

Baseline characteristics

Baseline characteristics of the total study population and the different groups (group 1 the total group, vaginal examination group 2 divided into a symptomatic group and an asymptomatic group and the non-responder group 3) are shown in table I.

No significant differences were found between group 1 and group 3 or between the asymptomatic women and the symptomatic women in group 2.

Table II The prevalence of POP stage in relation to the report of vaginal bulging in percentage (n)

	vaginal bulging	
	Symptomatic n=79	Asymptomatic n=570
stage 0	15.6 (12)	26.3 (146)
stage 1	20.8 (16)	39 (217)
stage 2A	18.1 (14)	17.8 (99)
stage 2B	16.9 (13)	10.1 (56)
stage 2C	7.8 (6)	3.7 (6)
stage 3	16.9 (13)	3.1 (17)
stage 4	3.9 (3)	0

(POP data were missing in six women vaginal bulging question had not been answered by ten women)

The prevalence of POP per POP stage in relation with vaginal bulging in our general population is presented in figure 2. The overall prevalence of ≥ stage 2B (all the women with stages 2B, 3 and 4) was 17.5% (n=114), of whom 30.7% had symptoms of vaginal bulging (n=35). The prevalence rates of vaginal bulging in relation with the POP stages in the symptomatic group (n=79) were as follows: 15.6% (n=12) in stage 0, 20.8%(n=16) in stage 1, 18.1% (n=14) in stage 2A, 16.9 % (n=13) in stage 2B, 7.8% (n=6) in stage 2C, 16.9% (n=13) in stage 3 and 3.9% (n=3) in stage 4. In the asymptomatic group (n=570) these rates were 26.3% (n=146) in stage 0, 39% (n=217) in stage 1, 17.8% (n=99) in stage 2A, 10.1% (n=56) in stage 2B, 3.7% (n=6) in stage 2C and 3.1% (n=17) in stage 3. There were no women with stage 4 POP (POP data were missing in six women vaginal bulging question had not been answered by ten women).

Table III Results of the multivariate logistic regression analysis with test scores and area under the curve (AUC) in POP substages 2A, 2B and 2C in relation to the hymen (pregn.POP = vaginal bulging symptoms during pregnancy with at least a little bother).

	distance ≥ -1 2A			distance ≥ 0 2B			distance ≥ 1 2C		
	OR	95 % CI		OR	95 % CI		OR	95 % CI	
Vaginal bulging	3.05	5.13	1.81	3.80	6.53	2.22	5.47	10.45	2.97
Age yrs				1.04	1.01	1.06	1.04	1.01	1.08
BMI							.94	.87	1.02
nulliparous				1.16	.31	4.30			
1 child	.44	.17	1.17				0	0	>1,000
2 children	1.56	.90	2.69	2.84	1.28	6.30	3.06	.97	9.70
>=3 children	1.54	.85	2.78	2.63	1.13	6.11	3.33	1.00	11.00
postmenopausal status	1.29	.86	1.94						
smoking current	.52	.33	.82	.62	.35	1.09	.57	.25	1.31
inc surgery	2.23	.92	5.41	2.11	.83	5.37			
educ level intermediate	.67	.39	1.14						
heavy work current	1.32	.85	2.04	.56	.92	2.66	1.53	.71	3.35
heavy work past							1.71	.88	3.32
pelvic girdle pain							.54	.19	1.55
pregn. POP	1.40	.95	2.07	1.44	.89	2.33			
mother POP	1.55	.99	2.42	1.96	1.22	3.15	2.00	1.00	3.97

Significance level .30

The results of the multivariate analyses on POP stages 2A, 2B and 2C are shown in table III. Significantly higher odds ratios were found especially in stages 2B (at the hymen) and 2C (beyond the hymen) for the report of vaginal bulging (3.80 and 5.47, resp.), for aging (1.04 and 1.04, resp.), parity of 2 (2.84 and 3.06, resp.), parity of ≥3 (2.63 and 3.33, resp.) and POP in the mother (1.96 and 2.00, resp.).

The Receiver Operating Characteristic (ROC) curve in figure 2 shows that the largest Areas Under the curve (AUC) were .759 for 'beyond the hymen' and .723 for 'at or beyond the hymen'. The AUC values were corrected for optimism .672 and .648, respectively. Due to small sample sizes, no ORs could be calculated in the multivariate analyses on HRT, hysterectomy, incontinence during pregnancy and incontinence in the mother.

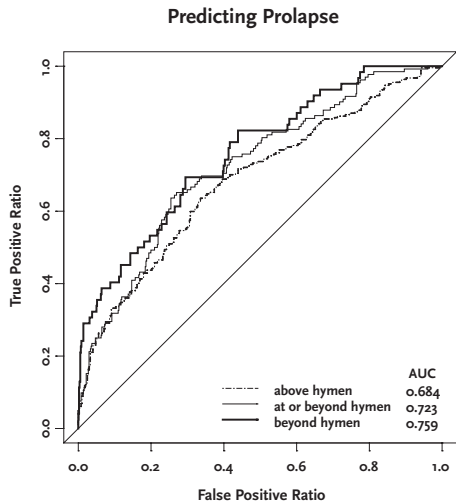


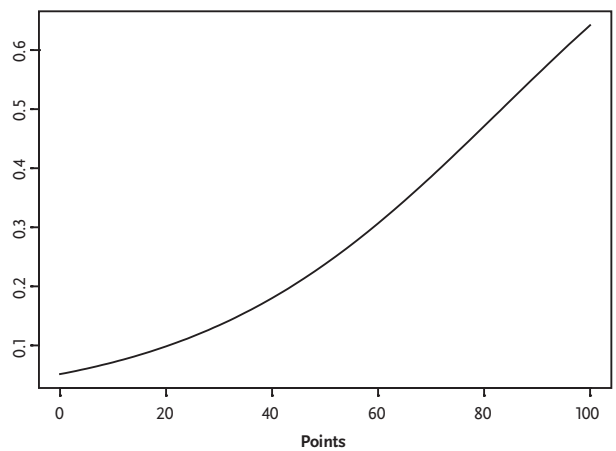
Figure 3 Receiver Operating Characteristics of the multivariate analysis with the Area Under the Curve of the stages 2A, 2B and 2C

In table IV, the Slieker-POP-Score-Chart and POP prognostic index are presented. The score chart is based on POP stage 2B (and 2C), i.e. POP at or beyond the hymen. After filling in the numbers on the score chart, the total score can be interpreted on the prognostic curve and will give the risk for the presence of POP in percentages. A shrinkage factor of 0.63, estimated from the bootstrap validation procedure, was applied to this model to enable optimal predictive performance in new subjects.

Table IV The Slieker-POP-Score-Chart and the prognostic index to read the SUM-score

									POP score
seeing/feeling bulge	yes	no							
score	24	0							
Age	45–49	50–54	55–59	60–64	65–69	70–74	75–79	80–84	85
Score	0	3	6	9	13	16	19	22	25
Children	0	1	2	≥ 3					
Score	0	3	19	17					
Smoking	yes	no							
Score	0	8							
incontinence surgery	yes	no							
Score	14	0							
current heavy work	yes	no							
Score	8	0							
POP symptoms gestation	yes	no							
Score	6	0							
mother with POP	yes	no							
Score	12	0							

prognostic index (SUM)



Discussion

The present study was designed to investigate the prevalence of POP in a general female population and to develop a prediction model based on prognostic factors that could be considered into a prognostic index.

Prevalence

The distribution of pelvic organ prolapse in this population indicated that POP was present at or beyond the hymen (≥ stage 2B) in 17.5% of the women. Within this 17.5%, 30.7% of the women had reported the symptom of seeing and/or feeling vaginal bulging. If stage 2A had been included, the prevalence would have increased to 34.9%, which is in line with the study by Gutman et al.[18] Our results are also comparable with those reported in many other studies, but as yet, no reliable explanation has been put forward for the discrepancy between POP stage and symptoms of vaginal bulging.[3,9,19-21] Explanations for the discrepancies between POP signs and POP symptoms might lie in the personal sphere, such as coping strategies, attitudes and beliefs, or in the social and economic circumstances, such as quality of life. We recommend that future research focuses on these personal and socio-economic factors in relation with POP.

Another possible underlying factor in the lack of conformity between the report of the symptom of vaginal bulging with the signs of POP stage is the reliability of the POPQ measurement. Results can be influenced by the level of fullness of the bladder and bowel and by reluctance to make a maximum valsalva manoeuvre on command during vaginal examination. We tried to standardize the measurements as much as possible to diminish this bias.

Our results are in contrast with a recent study by Kluivers et al.[22] who were able to distinguish symptomatic women with clinically relevant POP from asymptomatic women without any clinically relevant POP. These differences in outcome can be explained on the basis of population selection in the study by Kluivers et al.[22], because women were included who were seeking treatment for one or more pelvic floor disorders at a pelvic floor centre.

Prediction model

We developed a prediction model that has substantial sensitivity and specificity to help researchers estimate the prevalence of clinically relevant POP on a basis of a short questionnaire alone. To diagnose POP symptoms, we focused on the report of feeling and/or seeing vaginal bulging, as cornerstone of the symptom of POP, because in the literature, other variables, such as urinary splinting, digital manipulation, defaecation disorders and pelvic heaviness show no correlations with the presence of POP.[21,23,24]

In our study, the AUC was analysed based on risk factors presented in an earlier study [25], such as age, BMI, parity, menopausal status and HRT, smoking, hysterectomy, incontinence surgery, education level, heavy physical work currently or in the past, pelvic girdle pain, incontinence and/or the

report of vaginal bulging during pregnancy and incontinence or POP in the mother. Highest sensitivity and specificity were reached using the 2C score 'beyond the hymen' (AUC .759). However, the differences between the AUC of the cut-off points 'at' and 'beyond the hymen' are small. This indicates that no higher correlation is present between signs and symptoms using these cut-off points. Especially the report of vaginal bulging, age, parity ≥ 2 and POP in the mother contributed to the sensitivity and specificity of this prediction model. However, we recommend the use of 'at or beyond the hymen' as the cut-off point during POP examination instead of 'beyond the hymen'. Although the AUC was lower (.723), the difference was only small, but the advantage could be the early detection of POP. This approach might also enhance preventive strategies for more advanced POP stages.[26-29] Our findings are in line with Barber et al. [9] who studied the prevalence of clinically relevant POP (at or beyond the hymen) in what they referred to as a 'low risk' population, which is also applicable to a general population.

Higher AUC scores (of .90) were recently demonstrated in the study by Robinson et al. [23] with an artificial neural network in which 20 variables made the largest contributions to the prediction model, such as age, gravidity, parity, number of vaginal deliveries, weight of the largest vaginal delivery, BMI, menstrual status, number of years postmenopausal, race, history of chronic disease, hypertension, diabetes, chronic obstructive pulmonary disease, prior hysterectomy, prior prolapse or incontinence surgery and the use of anti-hypertensive's. In contrast, our study included family history, smoking behaviour, education, heavy physical work, pelvic girdle pain and POP symptoms during pregnancy. Furthermore, the definition of POP was different in the study by Robinson et al.. They defined clinically relevant POP as ≥ 2 cm beyond the hymen. The location of stages 2B and 2C 'at or beyond the hymen' was not used in their artificial neural network et al. Thus, the definition of POP (≥ 2 cm beyond the hymen) used by Robinson et al. can account for the high AUC score.

We developed and validated a simple, inexpensive tool, the Slieker-POP-Score-Chart, to predict the outcome of clinically relevant stage 2B (at or beyond the hymen) and 2C (beyond the hymen) POP with AUC scores of .640 and .672, respectively. This simple self-diagnostic instrument can also help women to estimate the severity of their POP. Until now, only a small number of women with POP seek treatment. Awareness of the potential presence of POP will encourage to seek advice on how to deal with their symptoms, or they can be advised to consult a gynaecologist or a physiotherapist for pelvic floor training [26-29] before surgery, because in our opinion, surgery is not the only treatment option.

Raising this awareness can also have an adverse effect on women being more aware of bulging feelings in the vagina, but if prevention is a goal, detection is important. Therefore the Slieker-POP-Score-Chart can not only used by midwifes but also on internet or other informative media and can be used for research to preventive strategies.

Strengths and limitations

One of the strengths of this study was the use of vaginal examination in a large cross-sectional design. This large study population was a subgroup of an even larger group of 95% of all eligible women of Brielle. Because there was no referral of the general practitioners and women were addressed directly by mail, there was no strong bias selection of the group. Another strength was that the results led to the development of a validated POP score instrument to estimate the presence of clinically relevant POP on the basis of eight questions, without the need for vaginal examination, which could also be helpful in epidemiological studies. Furthermore, this is a self-report instrument that can support a woman's decision to consult a physician.

This study also had limitations. A questionnaire can elicit socially desirable answers, although this was probably, minimal due to the anonymity of responses to the questionnaire. It can be difficult to identify POP, as the situation can change over the course of the day and there is considerable dependence on performing a maximum Valsalva manoeuvre. Although women were not selected by their physician, still, differences in outcome might have occurred because of selection bias in the population: women who experienced some POP symptoms could be more likely to agree for vaginal examination. This could cause overestimation of the real prevalence of POP.

Conclusion

The prevalence of POP symptoms in a general Dutch female population was 12.2%. The prevalence of POP, scored by the POPQ, 'at or beyond the hymen' (=≥ 2B) was 17.5% in the overall group. In the symptomatic group, 44.3% had POP stage ≥ 2B. With the newly developed prediction model (based on 17 questions) and the Slieker-POP-Score-Chart (based on eight questions) the risk of developing POP can be estimated by healthy women themselves. By researchers the Slieker-POP-Score-Chart can be used to estimate the prevalence of POP 'at or beyond the hymen' in a general Caucasian population.

References

1. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction (1996) Am J Obstet Gynecol Jul;175(1):10-7.
2. Bradley CS, Zimmerman MB, Wang Q, Nygaard IE (2008) Vaginal descent and pelvic floor symptoms in postmenopausal women: a longitudinal study. Obstet Gynecol May;111(5):1148-53.
3. Samuelsson EC, Victor FT, Tibblin G, Svardsudd KF (1999) Signs of genital prolapse in a Swedish population of women 20 to 59 years of age and possible related factors. Am J Obstet Gynecol Feb;180(2 Pt 1):299-305.
4. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL (1997) Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol Apr;89(4):501-6.
5. Fialkow MF, Newton KM, Lentz GM, Weiss NS (2008) Lifetime risk of surgical management for pelvic organ prolapse or urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct Mar;19(3):437-40.
6. Shah AD, Kohli N, Rajan SS, Hoyte L (2007) Racial characteristics of women undergoing surgery for pelvic organ prolapse in the United States. Am J Obstet Gynecol Jul;197(1):70 e1-8.
7. Drutz HP, Alarab M (2001) Pelvic organ prolapse: demographics and future growth prospects. Int Urogynecol J Pelvic Floor Dysfunct 2006 Jun;17 Suppl 1:S6-9.
8. Subak LL, Waetjen LE, van den Eeden S, Thom DH, Vittinghoff E, Brown JS (2001) Cost of pelvic organ prolapse surgery in the United States. Obstet Gynecol 2001 Oct;98(4):646-51.
9. Barber MD, Neubauer NL, Klein-Olarte V (2006) Can we screen for pelvic organ prolapse without a physical examination in epidemiologic studies? Am J Obstet Gynecol Oct;195(4):942-8.
10. Digesu GA, Chaliha C, Salvatore S, Hutchings A, Khullar V (2005) The relationship of vaginal prolapse severity to symptoms and quality of life. Bjog Jul;112(7):971-6.
11. Edwards, P, Roberts, I, Clarke, M, Diguiseppi, C, Pratap, S, Wentz, R, et al. (2002) Increasing response rates to postal questionnaires: systematic review. Bmj; 324:1183.
12. Van Der Vaart, CH, De Leeuw, JR, Roovers, JP, Heintz, Ap (2000) [The influence of urinary incontinence on quality of life of community-dwelling, 45-70 year old Dutch women] De invloed van urine-incontinentie op de kwaliteit van leven bij thuiswonende Nederlandse vrouwen van 45-70 jaar. Ned Tijdschr Geneeskd;144:894-7.
13. Van Brummen, HJ, Bruinse, HW, Van De Pol, G, Heintz, AP, Van Der Vaart, CH (2006) Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. Int Urogynecol J Pelvic Floor Dysfunct 17:224-30.
14. Swift S (2002) Current opinion on the classification and definition of genital tract prolapse. Curr Opin Obstet Gynecol Oct;14(5):503-7.

15. Steyerberg, E. W., Eijkemans M.J., et al. (2000). "Prognostic modelling with logistic regression analysis: a comparison of selection and estimation methods in small data sets." Stat Med 19(8): 1059-1079.
16. Schafer, J. L. and J. W. Graham (2002). "Missing data: our view of the state of the art." Psychol Methods 7(2):147-77.
17. Harrell FE, Jr., Lee KL and Mark DB (1996) Multivariable prognostic models: issues in developing models, evaluating assumptions and adequacy, and measuring and reducing errors. Stat Med 15, 361-87.
18. Gutman RE, Ford DE, Quiroz LH, et al. (2008)Is there a pelvic organ prolapse threshold that predicts pelvic floor symptoms? Am J Obstet Gynecol. Dec;199(6):683.e1-7.
19. Dietz HP, Eldridge A, Grace M, Clarke B (2004) Pelvic organ descent in young nulligravid women. Am J Obstet Gynecol Jul;191(1):95-9.
20. O'Boyle AL, O'Boyle JD, Ricks RE, Patience TH, Calhoun B, Davis G (2003) The natural history of pelvic organ support in pregnancy. Int Urogynecol J Pelvic Floor Dysfunct Feb;14(1):46-9.
21. Ellerkmann RM, Cundiff GW, Melick CF, Nihira MA, Leffler K, Bent AE (2001) Correlation of symptoms with location and severity of pelvic organ prolapse. Am J Obstet Gynecol 2001 Dec;185(6):1332-7.
22. Kluivers KB, Hendriks JC, Shek C, Dietz HP (2008) Pelvic organ prolapse symptoms in relation to POPQ, ordinal stages and ultrasound prolapse assessment. Int Urogynecol J Pelvic Floor Dysfunct Sep;19(9):1299-302.
23. Robinson CJ, Swift S, Johnson DD, Almeida JS (2008) Prediction of pelvic organ prolapse using an artificial neural network. Am J Obstet Gynecol Aug;199(2):193 e1-6.
24. Tan JS, Lukacz ES, Menefee SA, Powell CR, Nager CW (2005) Predictive value of prolapse symptoms: a large database study. Int Urogynecol J Pelvic Floor Dysfunct 2005;16:203-9.
25. Slieker-ten Hove, MCP, Pool-Goudzwaard AL, Eijkemans MJC, Steegers-Theunissen RPM, Burger CW, Vierhout ME. Symptomatic pelvic organ prolapse and possible risk factors in a general population, Am J Obstet Gynecol, accepted July 15, 2008.
26. Hagen S, Stark D, Maher C, Adams E (2004) Conservative management of pelvic organ prolapse in women. Cochrane Database Syst Rev (2):CD003882.
27. Jelovsek JE, Barber MD (2006) Women seeking treatment for advanced pelvic organ prolapse have decreased body image and quality of life. Am J Obstet Gynecol May;194(5):1455-61.
28. Jelovsek JE, Maher C, Barber MD (2007) Pelvic organ prolapse. Lancet Mar 24;369(9566):1027-38.
29. Bo K (2006) Can pelvic floor muscle training prevent and treat pelvic organ prolapse? Acta Obstet Gynecol Scand;85(3):263-8.

Chapter 6

Prevalence of pelvic organ prolapse symptoms and signs and their relationship to bladder and bowel disorders in a general female population

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Introduction In selected populations, pelvic organ prolapse (POP) was associated with bladder/bowel symptoms, but data on the general female population are lacking. Our aim was to obtain normative data on the prevalence of POP and pelvic floor dysfunction (PFD) symptoms and signs and to identify associations.

Methods Validated questionnaires on POP and PFD (Urogenital Distress Inventory (UDI) and Defaecation Distress Inventory (DDI)) were sent to a general population of 2979 women (aged 45-85 years). Data were analyzed using Kruskal-Wallis test, Chi-square test and Spearman's rank correlation coefficient.

Results Response rate was 62.7%. Associations between POP stage and parity (.002) and vaginal bulging (<.001) are significant. Anatomical locations of POP and PFD symptoms correlated significantly with incontinence of flatus, feeling anal prolapse, manual evacuation of stool, vaginal bulging, constipation and pain during faecal urge ($p \leq .005$).

Conclusions Strategies should be developed to alleviate obstructive bowel disorders associated with POP.

Keywords prevalence, incontinence, bladder, bowel, pelvic floor disorders, POPQ

Summary

POP was strongly associated with obstructive bowel disorders. Therefore, preventive strategies should be developed.

Introduction

Dysfunction of the pelvic floor (PFD) can cause many different symptoms, such as urinary or faecal incontinence [1-2], obstructed micturition or defaecation [3-4], sexual disorders [5-7], perineal pain [8] and vaginal bulging (a specific symptom of clinically relevant pelvic organ prolapse (POP)).[9] PFD symptoms are strongly associated with the female gender.[10] Parity is strongly associated with the development of PFD.[11] The impact of PFD symptoms is substantial and multidimensional [12], which underlines the need to gain more insight into associations between the different symptoms.

In clinical practice, women often present with a complexity of POP and bladder and/or bowel symptoms. Nevertheless, only weak correlations were found between POP and other bladder/bowel symptoms.[13-14] It appears that women with advanced POP are less likely to have stress urinary incontinence (SUI) but more likely to have obstructed micturation: SUI was only correlated with mild POP.[15] Recently, a stronger link has been demonstrated between bladder/bowel symptoms and vaginal descent.[16] Interestingly, not only the pelvic organ prolapse quantification (POPQ) stages were tested for correlations with bladder and bowel function, but also the anatomical location of POP was studied using the nine-point notation of the POPQ. Strong associations were found between bladder pain, obstructive bladder symptoms and the lowest point of the most dependent portion of the upper part of the anterior vaginal wall (point Ba) and between bowel incontinence and the lowest point of most dependent portion of the upper part of the posterior vaginal wall (point Bp). Furthermore, the C point was associated with vaginal bulging. This suggests that progression of vaginal descent over time is more strongly associated with these bladder/bowel symptoms than has so far been demonstrated. However, an association was found between POPQ location and bladder/bowel symptoms in a selected group of menopausal women, but the selection might have distorted the outcome. In 2005, Kahn et al. reported an association between faecal straining in combination with anterior vaginal wall and perineal descent in a selected population of women who visited the gynaecological clinic.[17]

It is unclear whether the associations between POP and bladder/bowel symptoms are also present in a general female population.

We therefore conducted a cross-sectional study to obtain normative data on the prevalence of pelvic floor dysfunction symptoms using questionnaires and vaginal examination. POPQ scores were tested in relation with age and parity. We also analysed associations between the pelvic floor symptoms and POPQ stages as well as the 9-point notation.

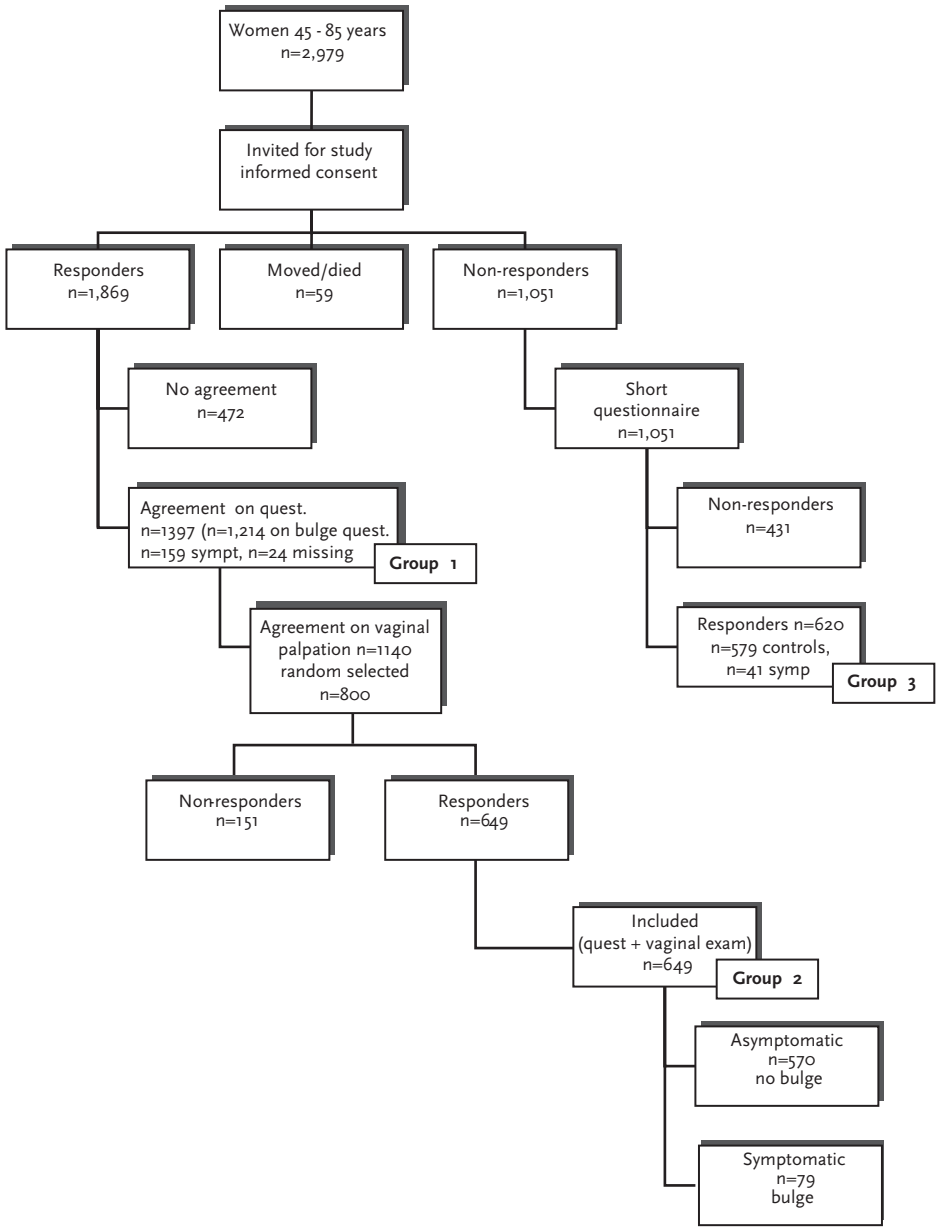

Figure 1 Flowchart of the study

Material and Methods

A cross-sectional study was performed on a general population of Dutch, mostly white women aged 45 to 85 years. Figure 1 presents the flowchart of the study.

The total population of women aged 45-85 years registered in the office records of eight out of nine general practitioners from the town of Brielle (near Rotterdam, the Netherlands), were approached to participate in the present study. Since all inhabitants have the obligation to be registered at a general practitioners clinic, the study population contained 95% of all women in Brielle in this age category. The women were sent information about the study and enrolled by filling out an informed consent form. They were offered three options: to sign a refusal form, or to fill out the questionnaire only or to fill out the questionnaire and undergo vaginal examination.

All the women were asked to complete a self-report questionnaire. Non-responders received a reminder eight weeks after the first contact that contained the same questionnaire. The data were collected anonymously. To avoid selection bias, non-responders were invited to complete a short questionnaire that comprised five questions about: age, parity, presence of stress urinary incontinence (yes/no), faecal incontinence (yes/no) and feeling a vaginal bulge (yes/no). To encourage a high response to the questionnaire, we used envelopes with the name and logo of the Erasmus University, coloured paper and stamped-addressed return envelopes.[18]

The questionnaire used in this study combined Dutch validated versions of pelvic floor questionnaires, such as the Urogenital Distress Inventory (UDI) [19] and the Defecation Distress Inventory (DDI).[2] In addition, women were asked about BMI ethnicity, educational level, parity, menopausal status, hormone replacement therapy (HRT), smoking, previous pelvic floor surgery, family history and heavy physical work currently or in the past.

Women were classified as symptomatic if they reported feeling and/or seeing vaginal bulging on the questionnaires. Differences in vaginal bulging, stress urinary incontinence (urine loss ≥1/month with at least a little bother) and faecal incontinence (loss of fluid or solid stool ≥1 / month with at least little bother) were tested between the non-responders and responders using the outcomes on the UDI and DDI. Women were defined symptomatic on bladder and bowel symptoms with the same criteria as mentioned for the vaginal bulging. Frequency of symptoms had to be reported at least ≥1/month and the bother was reported at least as ‘a little bother’.

Differences in vaginal bulging, stress urinary incontinence and faecal incontinence (loss of solid stool ≥1 / month with at least little bother) were tested between the non-responders and responders using the outcomes on the UDI and DDI.

Vaginal examination

From all the participants who gave informed consent to undergo vaginal examination, we randomly selected women for POPQ measurement. (All respond forms of the women were registered with a number that identified the age and they were at random taken by a research assistant). The POPQ was introduced by the International Continence Society (ICS). It has become widely accepted and proven to be valid [20] and reliable.[21] One gynaecologist and one physiotherapist performed the vaginal examinations (every women was examined by the gynaecologist or the physiotherapist). They practiced the vaginal examination protocol until both examiners were scoring same results. POPQ measurements were carried out in conformity with the ICS standardisation report.[20] After each examination, all the details were entered into the three-by-three POPQ grid. The two examiners were blinded to the results of the questionnaire. The women were asked to empty their bladder before the examination.

Women were assigned to one of five ordinal stages of prolapse (0 – 4) in accordance with the POPQ grading system. All methods, definitions and descriptions were in line with the ICS. Furthermore, we used the notation of the 9-point grid of the POPQ to analyse possible correlations between the different points of the POPQ.

Statistical analysis

Patient characteristics were compared between the POPQ stages and the symptomatic and asymptomatic women by means of the Kruskal-Wallis test and the Chi-square test for continuous and categorical variables, respectively. Spearman's rank correlation coefficient was calculated between the components of the 9-point grid of the POPQ and the items from the UDI and DDI questionnaires. The analyses were performed using the Statistical Package for Social Science (SPSS Inc) 15.0. The Medical Ethics Research Committee (METC) of the Erasmus MC in Rotterdam, the Netherlands, approved this study.

Results

Response rate

The response rate to the questionnaire was 62.7% (1,869/2,979). In the group of 1,869 responders, 472 (25.2%) women refused to participate, 1,397 (74.8%) women (group 1 in table I) agreed to fill out the large questionnaire and 1,140 (60.9%) agreed to fill out the questionnaire and undergo vaginal examination. Eight hundred women were selected at random and sent an invitation to undergo vaginal examination. Six-hundred forty-nine women participated (81.1%) in the vaginal examination. So, of the total study group of 1,397 46.4% were vaginally examined. The study group of 649 women (group 2) was stratified into an asymptomatic control group (n=570) and a symptomatic (n=79) group in which the women had reported seeing and/or feeling vaginal bulging. In the non-responder group 3, 59% returned the completed short questionnaire (620/1,051). Vaginal bulging was reported by 6.7% (n=41) of this non-responder group versus 9.8% in the responder group (135/1,397). Combining the data on the large and short questionnaires from the responders (group 1) and the initial non-responders (group 3) (1,397+620 = 2,017) revealed a prevalence rate of 8.7% (n=176) of feeling vaginal bulging.

Baseline characteristics

Baseline characteristics of the total study population and the different groups (overall group 1, the vaginal examination group 2 divided into a symptomatic group (seeing and/or feeling vaginal bulging) and an asymptomatic group and the non-responder group 3) are presented in table I.

No significant differences were found between group 1 and group 3, or between the asymptomatic and symptomatic women in group 2.

Table I Characteristics of total study group, the vaginal exam group and the non-responders group

	Questionnaire Group 1			Questionnaire and vaginal exam Group 2		Non- responders questionnaire Group 3
Characteristics of the study population	**Questionnaire Total**	**Total group bulging No**	**Total group bulging Yes**	**Vaginal exam bulging No**	**Vaginal exam bulging Yes**	**Non-responders**
	n=1,397[*)]	**n=1,214**	**n=159 (11.4 %)**	**n=570**	**n=79 (12,2%)**	**n=620**
Mean age	**58.0**	**57.8**	**59.0**	**58.0**	**59.3**	**59.2**
(range 45-84 years)	**(SD ± 9.2)**	**(SD ± 9.1)**	**(SD ± 9.5)**	**(SD ± 8.9)**	**(SD ± 9.1)**	
Mean BMI	**25.6 (SD ± 3.9)**	**25.6 (SD ± 4.0)**	**25.5 (SD ± 3.4)**	**25.6 (SD± 3.7)**	**25.5 (SD± 3.1)**	
Race	n=1,340	n=1,165	n=153	n=551	n=78	
White	1,351 (98.4)	1,172 (88.2)	156 (98.1)	545 (98.7)	78 (100)	
Non-white	20 (1.5)	18 (1.3)	1(0.6)	7 (1.3)	0	
Educational level	n=1,374	n=1,193	n=158	n=556	n=78	
Primary only	139 (9.9)	117 (9.8)	18 (11.4)	63 (11,3)	7 (8.9)	
Intermediate	1,039 (75.6)	907 (76)	117 (74.1)	420 (75.5)	60 (76.9)	
Higher	196 (14.3)	169 (14.2)	23 (14.6)	493 (88.6)	71 (91)	
Median parity	**2**	**2**	**2**	**2**	**2**	**2**
0	120 (8.9)	110 (9.4)	9 (5.8)	46 (8.3)	3 (3.8)	67 (10.6)
1	215 (16)	184 (15.8)	25 (16.3)	71 (12.9)	13 (16.6)	102 (16.1)
2	675 (50.3)	582 (49.9)	87 (56.8)	273 (49.5)	46 (58.9)	277 (43.6)
≥3	387 (28.8)	338 (29)	38 (24.8)	161 (29.2)	16 (20.5)	180 (28.3)
Menopausal status	n=1,383	n=1,202	n=159	n=557	n=79	
(Pre)menopausal	374 (27)	332 (27.6)	39 (24.5)	151 (27.1)	16 (20.2)	
Postmenopausal	1,009 (72.9)	870 (72.4)	120 (75.5)	406 (72.9)	63 (79.7)	
(Pre)menopausal with HRT	n=1,361	n=332	n=38	n=551	n=79	
(Pre)menopausal with HRT	24 (1.7)	22 (6.6)	2 (5.3)	9 (1.6)	0	
Postmenopausal with HRT	63 (4.6)	52 (15.6)	10 (26.3)	23 (4.2)	7 (8.9)	
Smoking	n=1,382	n=1,202	n=158	n=556	n=78	
Current Smoker	280 (20.2)	248 (22.4)	29 (10.5)	117 (21)	16 (20.5)	
Ever Smoker	345 (46.3)	300 (46.6)	43 (12.5)	158 (54.8)	25 (64.1)	
Surgical history	n=1,384	n=1,202	n=159	n=557	n=79	
Prolapse	103 (7.4)	71 (5.9)	29 (18.2)*	37 (6.6)	16 (20.2)	
Incontinence	47 (3.4)	36 (2.9)	10 (6.4)	21 (3.8)	3 (3.9)	
Hysterectomy	234 (16.9)	191 (15.8)	36 (22.6)	85 (15.3)	20 (25.3)	
Family history	n=985	n=874	n=97	n=397	n=44	
Mother POP	359 (26.4)	304 (34.8)	50 (51.5)*	139 (35)	22 (50)	
	n=870	n=784	n=86	n=357	n=41	
Mother UI	258 (29.6)	222 (28.3)	36 (41.9)	106 (29.7)	16 (39)	
Heavy physical work	n=1,381	n=1,198	n=159	n=553	n=79	
Current	269 (19.3)	227 (18.9)	39 (24.5)	109 (19.7)	18 (22.8)	
	n=1,384	n=1,201	n=159	n=556	n=79	
Ever	619 (44.3)	531 (44.2)	78 (49.1)	248 (44.6)	39 (49.3)	

Significant ($p < .05$)

Prevalence

The prevalence of POP per stage in relation with age in our general population is presented in table II. No significant association could be demonstrated between increasing age and increasing POP. In the analysis of the prevalence of POP in relation with parity, there was a significant association between POP stage and a parity of two (.002). No significant association was demonstrated between POP stage and a parity of ≥ 3.

In the vaginal examination group, the symptoms of pelvic floor dysfunction are shown in relation with the POPQ stages in table III. The only significant correlation between POP stage and bladder and/or bowel symptoms was with vaginal bulging ($p < .001$). In table IV, the symptoms of pelvic floor dysfunction are presented versus the nine-point notation of the POPQ measurement. Significant correlations (shown with) were found with incontinence of flatus, anal prolapse, manual evacuation of stool per vagina and/or anus, vaginal bulging, constipation and pain during faecal urge ($p \leq .05$). This demonstrated a strong association between the posterior vaginal wall and bowel disorders, as well as an association between bladder disorders and the anterior vaginal wall.

Table II Overall distribution of POP per age group (%)

Age (y)	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4	Total
45–50	24 (16.4)	66 (45.2)	53 (36.3)	3 (2.1)	0	146
>50–55	39 (26.9)	57 (39.3)	42 (29.0)	7 (4.8)	0	145
>55–60	47 (34.1)	39 (28.3)	45 (32.6)	7 (5.1)	0	138
>60–65	16 (20.5)	30 (38.5)	25 (32.1)	7 (9.0)	0	78
>65–70	21 (33.9)	17 (27.4)	22 (35.5)	2 (3.2)	0	62
>70	14 (18.9)	26 (35.1)	25 (33.8)	6 (8.1)	3 (4.1)	74
Overall	161 (25.0)	235 (36.5)	212 (33.0)	32 (5.0)	3 (.5)	643

Chi-square test for trend was used p <.001

Table III Symptoms of pelvic Floor disorders in the vaginal examination group versus the POPQ grading system in %.

	n=	stage 0	stage 1	stage 2	stage 3	stage 4	Overall
Urinary incontinence							
urge urinary incontinence	625	27.8	30.1	31.7	40.0	33.3	30.5
stress urinary incontinence	627	53.5	59.6	54.6	43.3	33.3	53.9
mixed urinary incontinence	624	22.2	25.4	25.9	16.7	0	24.2
Faecal incontinence							
flatus	638	46.9	46.4	54.5	58.1	33.3	49.6
fluid stool	638	15.0	8.2	15.6	9.7	0	12.3
solid stool	641	3.7	2.6	5.7	6.5	0	4
Obstructive micturition							
difficulty emptying bladder	631	14.5	17.7	20.7	33.3	33.3	18.7
bladder not empty after micturition	636	26.4	24.8	33.3	40.0	33.3	28.7
Obstructive defaecation							
false faecal urge	638	27.7	30.0	35.4	29.0	33.3	31.1
feeling of anal prolapse	634	15.2	12.9	19.9	16.7	66.7	16.2
manual evacuation of stool per vagina	633	12.7	14.4	16.0	22.6	33.3	15
manual evacuation of stool per anus	639	8.1	7.7	10.0	6.5	0	8.4
frequent straining during defaecation	637	27.8	27.9	30.2	35.5	0	3.5
Vaginal bulging	633	**7.6***	**6.9***	**15.8***	**43.3***	**100***	12.1
Constipation	637	7.5	4.3	4.7	0	0	5
Pain							
low abdominal	634	24.7	22.7	28.7	32.3	33.3	25.7
during faecal urge	633	10.8	7.8	11.8	19.4	0	10.4
during/after defaecation	632	12.7	10.4	14.2	16.1	0	13.6

Chi-square test (p-value <.001) was significant for bold text*

Table IV Symptoms of pelvic floor disorders versus the nine-point grid of the first notation of the POPQ with significance (*) in bold.

	aa	ba	c	hg	Per	tvl	ap	bp	d
Urinary incontinence									
urge urinary incontinence	–0,03	–0,08¶	0,01	–0,06	0,06	–0,02	0,05	0,03	–0,01
stress urinary incontinence	–0,03	–0,01	0,00	–0,05	0,02	–0,02	0,07	0,06	–0,02
mixed urinary incontinence	0,02	0,06	–0,02	0,04	–0,06	–0,01	–0,06	–0,05	0,00
Faecal incontinence									
flatus	–0,06	–0,06	0,01	–0,04	0,06	0,03	–0,09§	**–0,11****	0,01
fluid stool	0,01	–0,01	0,02	–0,02	–0,08	0,05	0,02	0,00	0,03
solid stool	–0,01	–0,04	0,03	–0,02	–0,03	0,05	0,02	0,04	–0,03
Obstructive micturition									
difficulty emptying bladder	–0,02	–0,05	–0,02	–0,02	0,00	–0,01	–0,06	–0,07	–0,02
bladder not empty after miction	–0,03	–0,02	–0,03	–0,04	–0,07	0,00	–0,07	–0,04	–0,06
Obstructive defaecation									
false faecal urge	–0,05	–0,07	–0,01	0,04	0,00	0,05	–0,02	–0,05	–0,01
feeling of anal prolapse	–0,02	–0,03	0,00	–0,03	–0,09§	0,01	–0,03	**–0,08*****	0,00
manual evacuation of stool per vagina	–0,04	0,01	–0,01	–0,02	0,06	0,00	**–0,08*****	**–0,11***	–0,03
manual evacuation of stool per anus	–0,02	–0,01	–0,04	0,07	–0,09§	**0,11***	–0,02	–0,02	–0,06
frequent straining during defaecation	0,02	0,02	0,02	–0,04	0,03	–0,01	–0,02	–0,09*	–0,02
Vaginal bulging	**–0,18***	**–0,18***	**–0,14***	–0,05	0,02	**0,10***	**–0,14***	**–0,11***	**–0,16***
Constipation	0,07	0,07	0,08¶	0,08¶	–0,05	0,02	0,05	0,06	0,03
Pain									
low abdominal	–0.03	–0.02	–0.01	–0.02	**–0.10***	–0.04	**–0.09***	–0.06	–0.04
during fecal urge	–0.04	–0.04	–0.08	–0.01	–0.04	–0.04	–0.04	–0.07	–0.05
during/after defecation	–0.01	0.00	0.01	0.03	–0.02	–0.02	0.00	–0.03	–0.03

Spearman's rank correlation coefficient was calculated between the components of the 9-point grid of the POPQ and the items from the UDI and DDI incontinence questionnaires.
*)*p* .000 **)*p* .01 ¶ 0.04 § 0.03 ***)*p* .05

Table V Detailed POPQ scores in the symptomatic and asymptomatic women with p-value ≤.005
Kruskal-Wallis was used to analyse the median and (the range)

	Bulging	No bulging	P value
Aa	–2 (–3, 3)	–3 (–3, 1)	**<.001**
Ba	–1 (–3, 6)	–2 (–4, 3)	**<.001**
C	–5 (–8, 6)	–6 (–9, 3)	**<.001**
GH	4 (2, 6)	4 (1, 8)	>.05
PB	3 (1, 6)	3 (1, 6)	>.05
TVL	9 (5, 10)	9 (3, 11)	**<.05**
Ap	–2 (–3, 3)	–3 (–3, 3)	**<.001**
Bp	–2 (–3, 6)	–2 (–3, 3)	**<.005**
D	–7 (–9, 1)	–7 (–9, –1)	**<.001**

*) *bold = significant*

Table V presents the detailed POPQ in relation with feeling and/or seeing vaginal bulging, The only non-significant locations were the genital hiatus, perineal length and total vaginal length.

Discussion

In this study on mainly white women aged 45-85 years from the general population, the prevalence of bladder and bowel disorders was high. We found a relation between the anterior compartment prolapse and urge urinary incontinence as well as a significant association between posterior compartment prolapse and bowel disorders. Analysis of the anatomical location of the POP led to these significant findings. The overall POPQ stage did not show any associations besides the symptom of vaginal bulging.

Prevalence of symptoms according to self-report questionnaires
In our overall group, the prevalence of feeling and/or seeing vaginal bulging in the overall group, was 12.1%: 9.7% reported the feeling of vaginal bulging alone. These figures are comparable with the prevalence of 8.3% (95% CI 7.3-9.1) reported in a Swedish population study.[11] In another Swedish study, only 4% had a positive POP score. However, they used other inclusion criteria and dichotomized the study population according to age and they defined a POP as a positive score on the question: 'do you experience a sense of heaviness in the lower abdomen'.[22] MacLennan et al. reported an 8% prevalence of POP in a general population.[10] They defined a positive POP symptoms based on the following question: do you have a feeling of something coming down in the vagina.'

Furthermore, their age group was age 15 - ≥ 65 years (28% were nulliparous and the number of deliveries in the parous group was unknown). They asked all the questions in a face-to-face interview, which may have led to different answers from those given on self-report questionnaires.[23]

Prevalence of signs scored with the POPQ grading system

In our general population, the percentage of women in the five ordinal POPQ stages (0-4) were 25%, 36.5%, 33%, 5% and 0.5%, respectively.

The prevalence of POP in a general population has only been determined using the POPQ grading system in a few studies. Our percentages in the five POP stages in the a*symptomatic* group 2, who did not report seeing and/or feeling vaginal bulging were comparable with those in the a*symptomatic* group in the study by Digesu et al.[24] However, there was a difference in mean age (48 years), which indicates that age may not be responsible for this comparable result, which also can be concluded from our findings that age and POP stage were not significant associated. In contrast, the data on the *symptomatic* group differed, probably due the different choice of definition of 'symptomatic'. In their symptomatic group, Digesu et al. included all the women with any type of prolapse complaints, such as bladder and bowel dysfunction and those who reported a 'sensation of dragging' or 'a lump or fullness in the vagina'.

In the literature, various populations of women have been studied. At first sight, the results of the prevalence of POP measured with the POPQ seems most comparable with the results reported by Swift [21] and Kahn [17], but they only recruited women who were receiving routine gynaecological health care. Thus, the characteristics of the study populations differed with respect to ethnicity, parity, BMI, age, surgical history and menopausal status, which hampers comparison of the prevalence rates in the POP stages.

In the prevalence study conducted by Nygaard et al., older women were enrolled from the Women's Health Initiative Hormone Replacement (WHIHR).[25] Their results are not comparable with ours due to the different age groups, BMI and the HRT (mean age 68.2 years, BMI 30.4). Furthermore, according to Nygaard et al., some degree of POP is nearly ubiquitous in older women. However, in our study, we did not observe a significant increase in POP with increasing age. The differences can probably be explained by patient selection, with different HRT scores, BMI and heavy physical work [26,27] in the population studied by Nygaard et al.

In our study, POP complaints were present in 3.8% of the nulliparous women. This indicates that childbirth is not a prerequisite for POP, although Boyle et al. demonstrated that pregnancy was associated with increased POP stages compared to nulliparous women.[26] In our study, the median parity

in the symptomatic and asymptomatic groups was similar (2). In the vaginal examination group, there was a significant (p .002) increase in POP with increasing parity, especially after the second child (OR 1.8). This is in line with the study by Mant et al.[28] who demonstrated that women with 2 children were 8.4 times more likely to develop POP that required hospital admission.

Pelvic floor symptoms versus POP signs measured with the POPQ, analysed with the grading system 0-4

In our study, no significant correlations were found between the pelvic floor symptoms of bladder and/or bowel disorders. However, we did find a significant correlation with 'seeing and/or feeling vaginal bulging'. Similar to the results of many other studies [10, 13, 21], we observed strong discrepancies between the symptoms and signs. Therefore, we emphasize the need for a clinically relevant definition of POP that is not only based on anatomical findings, but also on the symptoms.

Pelvic floor symptoms versus POP location measured with the POPQ, analysed with the nine-point notation

Although no significant correlations could be demonstrated between the pelvic floor symptoms and the ordinal POP stage (0-4 of the POPQ), many significant correlations were found between the anatomical locations of the nine-point notation. The presence of urge urinary incontinence was significantly associated with the lowest point of the upper anterior vaginal wall. This has been demonstrated in earlier studies and urge urinary incontinence disappeared or diminished after successful surgical correction of the anterior vaginal wall.[29]

Our results differed from those reported by Bradley et al.[16] Bladder pain and obstructive bladder symptoms were significantly associated with the lowest point of the upper anterior vaginal wall, but not with the presence of urge urinary incontinence. Overall, most of the significant associations were with obstructive bowel disorders: feeling of anal prolapse, manual evacuation of stool per vagina and per anus. Constipation and vaginal bulging were significantly associated with apical support and the genital hiatus. This is in line with the findings reported by Klingele et al.[4] POP severity was lower in their faecal incontinence group than in their obstructive bowel symptom group. The study by Bradley also demonstrated that vaginal bulging was associated with point C.[16] Our point C results contrasted with the study by Kahn [17], in which they did not find any significant association with constipation. However, Kahn et al. reported similar results on the need for manual evacuation of stool and straining associated with the lowest point on the upper posterior vaginal wall (point Bp). Therefore, the posterior vaginal wall is strongly as-

sociated with bowel disorders, including incontinence of flatus. It is likely that anatomical changes in the posterior vaginal wall are partly responsible for this symptom.

To analyse associations between POP symptoms and signs and bladder/bowel disorders in a general population, the POPQ grading system did not show as many significant associations as the nine point notation. This is not surprising, because the POPQ grading system only takes the most severely prolapsed compartment into account, which is not necessarily the compartment responsible for the most relevant symptoms. This demonstrates the need to present details about compartments when reporting on the prevalence of POP.

Strengths and limitations

POP varies between different ethnicities.[30] One of the strengths of our study was the ethnic homogeneity, because almost all of the women were white, which eliminated racial bias in the results. Furthermore, broad data were obtained from a large study group using a combination of questionnaires and vaginal examination.

Although this study was performed on a general population, the mean BMI of 25 and the 98% white race may have negative effects on extrapolation to other general populations. Also some selection bias could be present due to the women who participated in a vaginal examination and perhaps were symptomatic and never sought help in the past. Our data demonstrated important associations between bladder/bowel disorders and POP that will help to support the development of preventive strategies for pelvic floor disorders.

Conclusions

The prevalence of bladder and bowel disorders was high. Anterior compartment prolapse was related to urge urinary incontinence. Posterior compartment prolapse was associated with bowel disorders. To demonstrate significant associations between the presence of POP and bowel/bladder disorders, it is essential to analyse not only the overall POP-Q stages, but also the prolapse severity in the three compartments. As POP was found to be strongly associated with obstructive bowel disorders, preventive strategies need to be developed.

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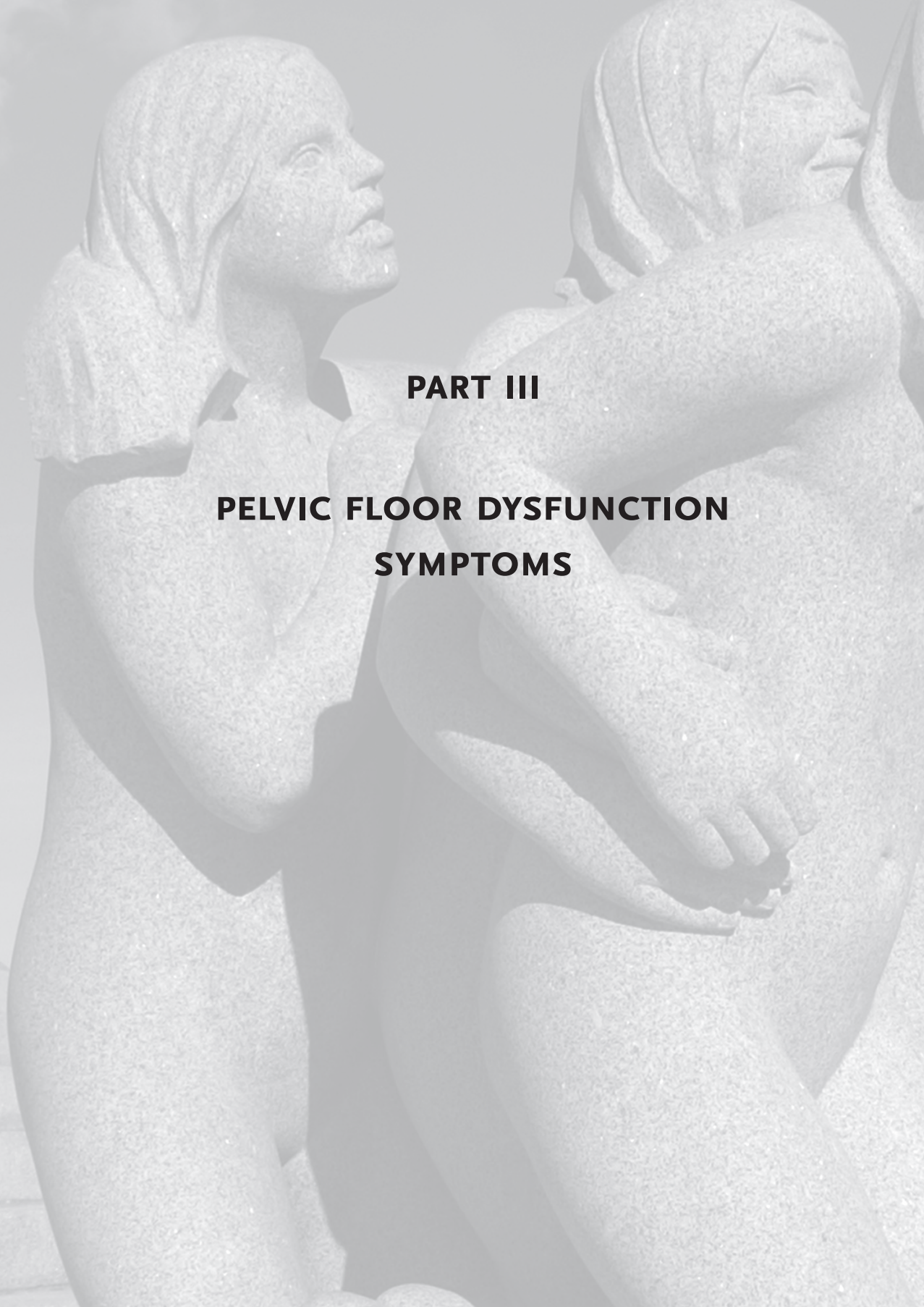
References

1. Hunskaar S, Lose G, Sykes D, Voss S (2004) The prevalence of urinary incontinence in women in four European countries. BJU Int;93:324-30.
2. Van Brummen HJH, Bruinse HW, Van De Pol G, Heintz Ap, Van Der Vaart CH. (2006) Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. Int Urogynecol J Pelvic Floor Dysfunct;17:224-30.
3. Richter HE, Nygaard I, Burgio KL, Handa VL, Fitzgerald MP, Wren P et al. (2007) Lower urinary tract symptoms, quality of life and pelvic organ prolapse: irritative bladder and obstructive voiding symptoms in women planning to undergo abdominal sacrocolpopexy for advanced pelvic organ prolapse. J Urol 178:965-9; discussion 969.
4. Klingele CJ, Carley ME, Hill RF (2002) Patient characteristics that are associated with urodynamically diagnosed detrusor instability and genuine stress incontinence. Am J Obstet Gynecol 186:866-8.
5. Mouritsen L (2005) Classification and evaluation of prolapse. Best Pract Res Clin Obstet Gynaecol 19:895-911.
6. Handa VL, Cundiff G, Chang HH, Helzlouer KJ (2008) Female Sexual Function and Pelvic floor disorders. Obstet Gynecol 111:1045-1052.
7. Rogers GR, Villarreal A, Kammerer-Doak D, Qualls C (2001) Sexual function in women with and without urinary incontinence and/or pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunction 12:361-5.
8. Albers LL, Borders N. (2007) Minimizing genital tract trauma and related pain following spontaneous vaginal birth. J Midwifery Womens Health 52:246-53.
9. Tan, JS, Lukacz, ES, Menefee, SA, Powell, CR, Nager, CW. Predictive value of prolapse symptoms: a large database study. Int Urogynecol J Pelvic Floor Dysfunct 2005;16:203-9; discussion 209.
10. Maclennan AH, Taylor AW, Wilson DH, Wilson D. (2000) The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. Bjog 107:1460-70.
11. Tegerstedt G, Maehle-Schmidt M, Nyren O, Hammarstrom M (2005) Prevalence of symptomatic pelvic organ prolapse in a Swedish population. Int Urogynecol J Pelvic Floor Dysfunct 16:497-503.
12. Swithinbank LV, Donovan JL, Du Heaume JC, Rogers CA, James MC, Yang Q et al (1999) Urinary symptoms and incontinence in women: relationships between occurrence, age, and perceived impact. Br J Gen Pract 49:897-900.
13. Ellerkmann RM, Cundiff GW, Melick CF, Nihira MA, Leffler K, Bent AE (2001) Correlation of symptoms with location and severity of pelvic organ prolapse. AM J Obstet Gynecol 185:1332-7; discussion 1337-8.
14. Weber AM, Walters MD, Ballard La, Booher DL, Piedmonte MR (1998) Posterior vaginal prolapse and bowel function. Am J Obstet Gynecol 179:1446-9; discussion 1449-50.

15. Burrows LJ, Meyn LA, Walters MD, Weber AM (2004) Pelvic symptoms in women with pelvic organ prolapse. Obstet Gynecol 104:982-8.
16. Bradley CS, Zimmerman MB, Wang Q, Nygaard IE (2008) Vaginal descent and pelvic floor symptoms in postmenopausal women: a longitudinal study. Obstet Gynecol 111:1148-53.
17. Kahn MA, Breitkopf CR, Valley MT, Woodman PJ, O'Boyle AL, Bland DI et al (2005) Pelvic Organ Support Study (POSST) and bowel symptoms: straining at stool is associated with perineal and anterior vaginal descent in a general gynecologic population. AM J Obstet Gynecol 192:1516-22.
18. Edwards, P, Roberts, I, Clarke, M, Diguiseppi, C, Pratap, S, Wentz, R, et al (2002) Increasing response rates to postal questionnaires: systematic review. Bmj 324:1183.
19. Van Der Vaart CH, De Leeuw JR, Roovers JP, Heintz AP (2002) [The influence of urinary incontinence on quality of life of community-dwelling, 45-70 year old Dutch women] De invloed van urine-incontinentie op de kwaliteit van leven bij thuiswonende Nederlandse vrouwen van 45-70 jaar. Ned Tijdschr Geneeskd 144:894-7.
20. Bump RC, Mattiasson A, BO K, et al (1996) The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. AM J Obstet Gynecol 175:10-7.
21. Swift S (2002) Current opinion on the classification and definition of genital tract prolapse. Curr Opin Obstet Gynecol Oct;14(5):503-7
22. Eva UF, Gun W, Preben K (2003) Prevalence of urinary and fecal incontinence and symptoms of genital prolapse in women. Acta Obstet Gynecol Scand 82:280-6.
23. Khullar V, Damiano R, Toozs-Hobson P, Cardozo L (1998) Prevalence of faecal incontinence among women with urinary incontinence. BR J Obstet Gynaecol 105:1211-3.
24. Digesu GA, Chaliha C, Salvatore S, Hutchings A, Khullar V (2005) The relationship of vaginal prolapse severity to symptoms and quality of life. Bjog 112:971-6.
25 Nygaard I, Bradley C, Brandt D (2004) Pelvic organ prolapse in older women: prevalence and risk factors. Obstet Gynecol 104:489-97.
26. O'Boyle AL, Woodman PJ, O'boyle JD, Davis GD, Swift SE (2002) Pelvic organ support in nulliparous pregnant and nonpregnant women: a case control study. Am J Obstet Gynecol 187:99-102.
27. Woodman, PJ, Swift, SE, O'boyle, AL, Valley, MT, Bland, Dr, Kahn, MA, et al. Prevalence of severe pelvic organ prolapse in relation to job description and socioeconomic status: a multicenter cross-sectional study. Int Urogynecol J Pelvic Floor Dysfunct 2006;17:340-5.
28. Mant J, Painter R, Vessey M (1997) Epidemiology of genital prolapse: observations from the Oxford Family Planning Association Study. Br J Obstet Gynaecol 104:579-85.
29. Batra AK, Mathews R, Lopresti A, Initial experience with the modified vaginal wall sling in the treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1997;8(4):209-12.
30. Hoyte L, Thomas J, Foster Rt, Shott S, Jakab M, Weidner AC (2005) Racial differences in pelvic morphology among asymptomatic nulliparous women as seen on three-dimensional magnetic resonance images. Am J Obstet Gynecol 193:2035-40.



PART III

PELVIC FLOOR DYSFUNCTION SYMPTOMS

Chapter 7

Prevalence of double incontinence, risks and influence on quality of life in a general female population

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Background Urinary (UI) and anal incontinence (AI) are complaints that have enormous impact on quality of life (QOL). Few data are available on the prevalence of double incontinence (DI) in the general female population.
Objective To determine the prevalences of UI, AI and DI, their associations with age and parity and their effects on QOL.
Design, setting and participants Cross-sectional study on a general female population, aged 45-85 years, the Netherlands.
Measurements Validated questionnaires were used to measure pelvic floor dysfunction and QOL. A short questionnaire was used to obtain data from non-responders. Analysis were performed with Chi-square tests, ANOVA and logistic regression.
Results Response rate was 62.7% (1,869/2,979); 59% of the non-responders filled in the short questionnaire (620/1,051). No significant differences in stress urinary incontinence, vaginal bulging, solid stool incontinence and parity were found between the responders and the non-responders. DI and DIF (DI including flatal incontinence) were reported by 10.3% and 35.4% of the women, respectively. Women with urge urinary incontinence (UUI) alone had an odds ratio (OR) of 4.3 (95% CI 2.4-7.9) for liquid stool incontinence, 1.6 (95% CI 0.5-4.9) for solid stool incontinence and 2.4 for flatal incontinence (95%CI 1.5-3.8). Women with AI had an OR of 5.8 (95% CI 1.8-18.2) for UUI. Women with DIF reported significantly poorer QOL. A limitation of the study was the lack of objective clinical validation of symptoms, which may have influenced the real prevalence data.
Conclusions The most important relation was found between UUI and liquid stool incontinence (OR 4.3). We recommend that clinicians take the history of patients with UUI or mixed urinary incontinence to exclude the co-existence of any form of AI.

Introduction

Urinary incontinence (UI) and anal incontinence (AI) are symptoms of pelvic floor dysfunction (PFD) that can affect women of all ages.[1,2] Although UI and AI are not life-threatening, they have very serious impact on physical, psychological and social well-being.[3] In the literature, prevalence rates of UI and AI vary due to the use of a wide variety of questionnaires, definitions, study populations and selection criteria.[4]

A considerable number of women have UI and AI simultaneously [4,5]. This double incontinence (DI) is probably the most severe and debilitating manifestation of pelvic floor dysfunction.[5] Prevalence rates of DI in women vary from 5 to 69%.[4] Data collection from selected groups who are receiving care for their problems instead of a general population might be the cause of this wide range on prevalence estimates.[6-9] Until recently, only one study on the prevalence of DI has focused on a general population. However, the study population were all older than 60 years.[10] As data on the prevalence of UI, AI and DI are lacking in the general population, the aim of this study was to estimate the prevalence of UI, AI and DI in relation with age and parity and their effects on the quality of life in a general population of women, stratified into 5-year age groups of between 45 and 85 years. Furthermore, odds ratios (ORs) were calculated for UI in the presence of AI and vice versa. We used the definitions specified by the International Continence Society.

Material and methods

A cross-sectional study was performed on a general population of women, mostly of Caucasian origin, aged from 45 to 85 years. Figure 1 presents the flowchart of the study design.

The total population of women aged 45-85 years (n=2,921 out of 16,000 citizens) registered in the patient lists of eight out of the nine general practices in the town of Brielle (near Rotterdam, the Netherlands) were approached to participate in the present study. As all the inhabitants are obliged to register with a general practitioner, the study population included 95% of the women in this age range. The women were sent information about the study and they could enrol by filling out an informed consent form. All the women were asked to complete a self-report questionnaire. Non-responders received a reminder eight weeks later that contained the same questionnaire. Data were collected anonymously. To check for selection bias, non-responders were invited to complete a short questionnaire that comprised five questions about: age, parity, presence of stress urinary incontinence (yes/no), faecal incontinence (yes/no) and feeling vaginal bulging (yes/no). To encourage a high re-

sponse to the questionnaire, we used envelopes with the name and logo of the Erasmus University, coloured paper and stamped-addressed return envelopes.[11] Each reminder included the same questionnaire.

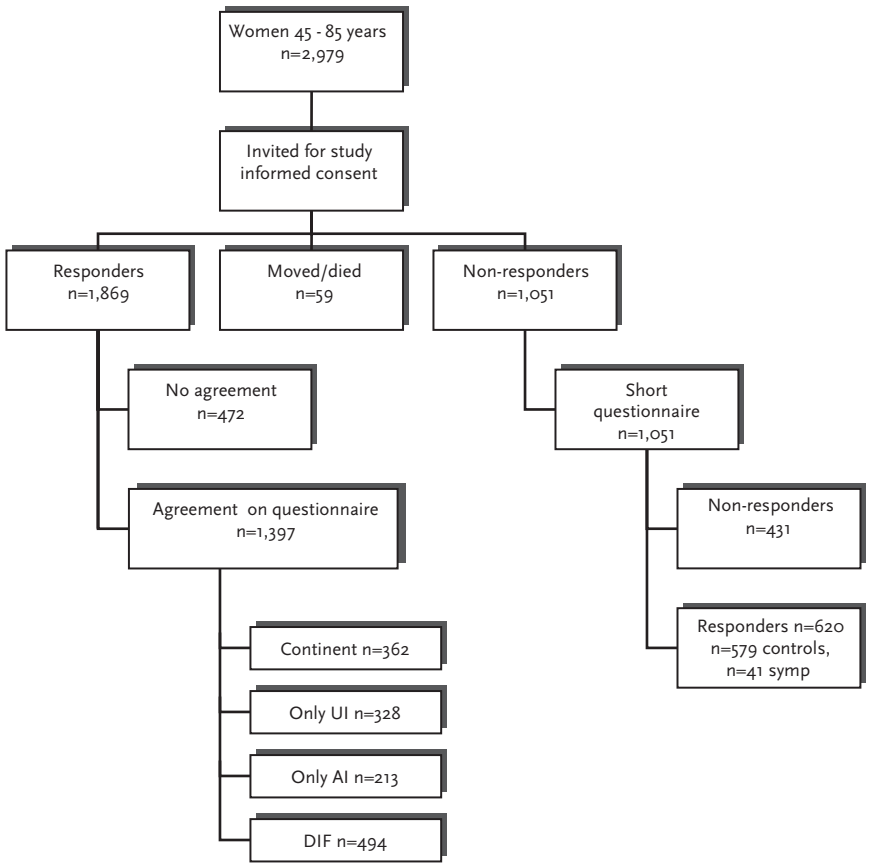

Figure 1 Flowchart of the study (UI= urinary incontinence, AI= anal incontinence, DIF= double incontinence including flatus)

Table I Abbreviations

UI	Urinary Incontinence
UUI	Urge Urinary Incontinence
SUI	Stress Urinary Incontinence
MUI	Mixed Urinary Incontinence. Both SUI and UUI
FlI	Flatus incontinence
LSI	Liquid Stool Incontinence
SSI	Solid Stool Incontinence
FI	Faecal incontinence (LSL and/or SSL)
AI	Anal incontinence (LSL and/or SSL and/or Flatus)
DI	Double incontinence: UI and FI
DIF	Double incontinence: UI and AI (including flatus)

Self-report postal questionnaire

The questionnaire used in this study combined several validated Dutch versions of pelvic floor questionnaires, such as the Urogenital Distress Inventory (UDI) [3] and the Defaecation Distress Inventory (DDI).[12] In addition, subjects were asked about body mass index (BMI), ethnicity, parity, family history, menopausal status, hormone replacement therapy (HRT) and educational level. To measure quality of life, the validated Euroqol EQ-5D was used.[13] This EQ-5D is a validated health-related quality of life questionnaire with five domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) that are scored on a 3-point Likert scale. An EQ-Visual Analogue Scale (VAS) was also included to record current health-related quality of life.

To answer the questions about bladder and bowel symptoms, the presence or absence of a particular symptoms had to be indicated first. If present, the women were asked to indicate the amount of bother being caused by that symptom (none, a little, quite a lot or a lot) as well as the frequency at which it occurred (daily, a few times a week, once a week or once a month). Symptoms were included in the analysis when at least a little bother was scored. Questions about frequency and bother were only asked in relation with the individual symptoms, not in combinations. The women were divided into four urinary incontinence groups: 1) no urinary incontinence, 2) stress urinary incontinence (SUI) alone, 3) urge urinary incontinence (UUI) alone and 4) SUI and UUI.

To define AI, we followed the ICI report 2005 [14] that makes a clear distinction between AI and faecal incontinence (FI): AI includes the flatal incontinence.(FlI)

AI was divided into eight different groups: 1) no anal incontinence, 2) FlI alone, 3) liquid stool incontinence alone (LSI), 4) solid stool incontinence (SSI) alone, 5) FlI and LSI, 6) FlI and SSI 7) LSI and SSI and 8) FlI and LLI and

SSI. Women with any form of UI and FI were designated as having double incontinence (DI). The abbreviation DIF refers to the group of women with DI including FlI. Furthermore, distinction was made between the symptoms by selecting a solitary symptom (e.g. SUI alone) and different combinations of solitary symptoms. An overview of the abbreviations used is presented in table I.

Respondents were asked to answer the questions based on their symptoms over the past 12 months.

Statistical analysis

Age group and parity were analysed in the UI group and AI group using Chi-square tests for categorical variables. Analysis of Variance (ANOVA) was performed on the quality of life utility scores from the EuroQoL-5D. Associations between UI and each of the AI components FlI, LSI and SSI were assessed with logistic regression analyses, with adjustment for age, parity and menopausal status. The same was done to detect associations between AI and the presence or absence of UUI or SUI. Associations were expressed as odds ratios (ORs) and 95% confidence intervals (95% CI). P values of $< .05$ were considered to be statistically significant. The analyses were performed using the Statistical Package for Social Science (SPSS Inc 15.0).

Table II Characteristics of the study population

Characteristics of the study population	Questionnaire Total n=1,397*	Continent n=525	UI*) n=679	FI*) n=50	DI*) n=143	p-value
Mean age (range 45-84)	58.0 (SD ± 9,2)	58.7 (SD ± 9,0)	56.9 (SD ± 9,0)	59 (SD ± 8,8)	60.1 (SD ± 9.9)	**<.001**
Mean BMI	25.6 (SD ± 3.9)	25.3 (SD ± 4.0)	25.9 (SD ± 3,8)	23.8 (SD ± 3.2)	26.2 (SD ± 4.3)	**<.005**
Race						
White	1,351 (98.4)	508 (99.6)	657 (98.1)	48 (96)	138 (97.9)	
Non-white	20 (1.5)	2 (.4)	13 (1.9)	2 (4)	3 (2.1)	
Educational level	n=1,374	n=515	n=667	n=50	n=142	
Primary only (low level)	139 (10.1)	64 (12.4)	50 (7.5)	5 (10)	20 (14.1)	
Intermediate	1,039 (75.6)	451 (87.6)	617 (92.5)	45 (90)	122 (85.9)	
Higher	196 (14.3)	68 (13.2)	94 (14.1)	10 (20)	24 (16.9)	
Mean parity (range 0-10)	2.3 (SD± 1.1)	2.3 (SD ± 1.1)	2.3 (SD± 1.0)	2.2 (0.8)	2.3 (SD ± 1.3)	
Median parity	2	2	2	2	2	
0	120 (8.9)	47 (9)	49 (7.2)	8 (16)	16 (11.2)	
1	215 (16)	87 (16.6)	100 (14.7)	6 (12)	22 (15.4)	
2	675 (50.3)	244 (46.5)	340 (50.1)	26 (52)	65 (45.5)	
≥3	387 (28.8)	147 (28)	190 (28)	10 (20)	40 (28)	
Menopausal status	n=1,383	n=519	n=672	n=50	n=142	
Menopausal	374 (27)	123 (23.7	211 (31.4)	12 (24)	28 (19.7)	
Postmenopausal*)	1,009 (72.9)	396 (76.3)	461 (68.6)	38 (76)	114 (80.3)	**<.05**
Smoking	n=1,382	n=522	n=668	n=50	n=142	
Current Smoker	280 (20.2)	94 (18)	144 (21.6)	8 (16)	34 (23.9)	
Ever Smoker	345 (46.3)	121 (51.1)	174 (53.9)	13 (61.9)	37 (52.1)	
Surgical history	n=1,384	n=520	n=672	n=50	n=142	
Prolapse	103 (7.4)	41 (7.9)	42 (6.3)	8 (16)	12 (8.5)	
	n=1,382	n=519	n=672	n=50	n=141	
Incontinence	47 (3.4)	11 (2.1)	23 (3.4)	3 (6)	10 (7.1)	
	n=1,383	n=518	n=675	n=49	n=141	
Hysterectomy	234 (16.9)	83 (16)	116 (17.2)	8 (16.3)	27 (19.1)	
Family history	n=985	n=377	n=485	n=35	n=88	
Mother POP	359 (26.4)	124 (32.9)	180 (37.1)	13 (37.1)	42 (47.7)	
	n=870	n=366	n=416	n=33	n=71	
Mother UI	258 (29.6)	55 (15)	162 (38.9)	10 (30.3)	37 (52.1)	**<.001**
Heavy physical work	n=1,381	n=516	n=672	n=50	n=143	
Current	269 (19.4)	92 (17.8)	146 (21.7)	10 (20)	21 (14.7)	
	n=1,381	n=518	n=673	n=50	n=143	
Ever	619 (44.7)	216 (41.7)	317 (47.1)	20 (40)	77 (53.8)	

* *missing data were excluded from the analysis*

*) *UI=urinary incontinence, FI=faecal incontinence, DI double incontinence. Postmenopausal=women having their last bleeding at least one year ago.*

Results

The response rate was 62.7% (1,869/2,979). In the non-responder group (n=1,051), another 620 women completed the short questionnaire. Despite the intimate nature of the questions, only 3% of the questions remained unanswered. Relevant baseline characteristics of the total study population are shown in table II. In the non-responder group, 59% filled in and returned the non-responder questionnaire (620/1,051). Scores in this non-responder group were not significantly different from those in the total study group.

Significant differences were found in body mass index (BMI), menopausal status and a family history of a mother with UI between the continent women and the different incontinent groups ($p < .005$). Table III presents the prevalences of UI and Al in the different age groups. In the age groups shown in table III, the DIF score was significant ($p < .001$). Bother scores from bladder and bowel symptoms were higher in SSI, LSI and UUI than in FlI and SUI. There was a significant correlation between an increase in the occurrence of complaints and increased bother ($p < .005$) (data not shown). The prevalence of FlI was significantly higher in the postmenopausal women (50.3%) than in the premenopausal women (40.2%) ($p < .001$). Table IV shows that there was no significant increase in the prevalence of UI with increasing parity. The ORs for UI and AI, after correction for age, parity and menopausal status, are presented in table V. UUI and mixed urinary incontinence (MUI) were significantly associated with LSI, SSI and FlI.

There was a high chance that women with UI also had AI and vice versa. Women with UUI alone had ORs of 4.3 (95% CI 2.4-7.9) for LSI, 1.6 (95% CI 0.5-4.9) for SSI and 2.4 for FlI (95% CI 1.5-3.8). Women with SUI alone had ORs of 1.3 (95% CI 0.8-2.1) for LSI and 0.4 (95% CI 0.1-1.0) for FlI. Women with AI (FlI + LSI + SSI) had an OR of 5.8 (95% CI 1.8-18.2) for UUI. Quality of life according to the EQ-5D (table VI) was dramatically lower in all the incontinent groups than in the continent group, with the lowest score in relation with DIF (.7960 versus .8500 in the continent women). On the EQ-VAS scores were especially low in the DI group compared to the continent women.

Table III Symptoms of continence and incontinence versus age

	45-50	>50-55	>55-60	>60-65	>65-70	>70	Total	p value
UI								**.064**
No incontinence	77 (22.5)	82 (26.4)	65 (24.6)	47 (26.9)	44 (33.1)	47 (27.3)	362 (25.9)	**< .01**
only SUI	131 (38.5)	90 (29.6)	85 (33.6)	51 (30.5)	25 (19.7)	30 (18.9)	412 (30.5)	
only UUI	15 (4.4)	19 (6.3)	12 (4.7)	12 (7.2)	6 (4.7)	18 (11.3)	82 (6.1)	
Mixed UI	76 (22.4)	72 (23.7)	56 (22.1)	30 (18.0)	31 (24.4)	48 (30.2)	313 (23.2)	
AI								**< .001**
no AI	183 (53.7)	162 (52.6)	114 (43.5)	72 (43.1)	62 (47.7)	75 (44.4)	668 (48.5)	
only Flatus	125 ((36.7)	102 (33.1)	113 (43.1)	72 (43.1)	46 (35.4)	57 (33.7)	515 (37.4)	
only LSI	13 (3.8)	11 (3.6)	4 (1.5)	4 (2.4)	6 (4.6)	5 (3.0)	43 (3.1)	
only SSI	2 (.6)	2 (.6)	2 (.8)	1 (.6)	0	2 (1.2)	9 (.7)	
Flatus and LSI	15 (4.4)	22 (7.1)	25 (9.5)	13 (7.8)	10 (7.7)	19 (11.2)	104 (7.6)	
Flatus and SSI	2 (.6)	3 (1)	2 (.8)	4 (2.4)	1 (.8)	5 (3)	17 (1.2)	
LSI and SSI	0	3 (1)	1 (.4)	0	0	1 (.6)	5 (.4)	
Flatus and LSI and SSI	1 (.3)	3 (1)	1 (.4)	1 (.6)	5 (3.8)	5 (3)	16 (1.2)	
any FI	33 (9.7)	45 (14.5)	35 (13.4)	24 (14.2)	22 (16.9)	38 (22.2)	197 (14.2)	**< .001**
DI								
DI	24 (7)	33 (10.6)	27 (10.2)	16 (9.4)	12 (9.3)	31 (18.1)	143 (10.3)	**< .01**
DIF	114 (33.3)	101 (32.5)	107 (40.5)	60 (34.3)	42 (31.6)	70 (40.7)	494 (35.4)	**<.000**

Age groups were compared between the groups of no incontinence, UI and between groups of AI, using Chi-square tests for categorical variables (age group in 10-years)

Table IV Parity versus incontinence Parity was compared between the groups of UI and between groups of AI, using Chi-square tests for categorical variables (parity).

	0	1	2	≥ 3	total
UI					
No incontinence	54 (47.0)	89 (42.6)	255 (39.1)	145 (38.9)	543 (40.2)
only SUI	35 (30.4)	65 (31.1)	196 (30)	116 (31.1)	412 (30.5)
only UUI	7 (6.1)	11 (5.3)	37 (5.7)	27 (7.2)	82 (6.1)
Mixed UI	19 (16.5)	44 (21.1)	165 (25.3)	85 (22.8)	313 (23.2)
AI					
no AI	60 (50.4)	107 (50.2)	332 (49.8)	169 (44.7)	668 (48.5)
only Flatus	35 (29.4)	78 (36.6)	244 (36.6)	158 (41.8)	515 (37.4)
only LSI	4 (3.4)	8 (3.8)	19 (2.8)	12 (3.2)	43 (3.1)
only SSI	0	1 (.5)	3 (.4)	5 (1.3)	9 (.7)
Flatus and LSI	15 (12.6)	15 (7)	52 (7.8)	22 (5.8)	104 (7.6)
Flatus and SSI	1 (.8)	2 (.9)	8 (1.2)	6 (1.6)	17 (1.2)
LSI and SSI	1 (.8)	1 (.5)	3 (.4)	0	5 (.4)
Flatus and LSI and SSI	3 (2.5)	1 (.5)	6 (.9)	6 (1.6)	16 (1.2)
DI					
DI	16 (13.3)	22 (10.3)	65 (9.7)	40 (10.5)	143 (10.3)
DIF	40 (33.3)	70 (32.6)	236 (35.0)	148 (38.2)	494 (35.4)

No significance, (p value <.005)

Table V Risk estimates of all different forms of incontinence and continence (corrected for age, parity and menopause.

		Risk estimates
	LSI	
No UI	7.1 (38/538)	1
Only UUI	24.7 (20/81)*	4.3 (CI 2.4 – 7.9)
Only SUI	9.2 (38/411)*	1.3 (CI .8 – 2.1)
MUI	21.1 (66/313)*	3.5 (CI 2.3 – 5.4)
	SSI	**Risk estimates**
No UI	3.1 (17/540)	1
Only UUI	4.9 (4/81)*	1.6 (CI .5 – 4.9)
Only SUI	1.2 (5/411)	.4 (CI .1 – 1.0)
MUI	5.8 (18/312)*	1.9 (CI .9 – 3.7)
	Flatus	**Risk estimates**
No UI	35.6 (192/540)	1
UUI	56.8 (46/81)*	2.4 (CI 1.5 – 3.8)
SUI	53.0 (218/411)*	2.0 (CI 1.6 – 2.7)
MUI	59.4 (184/310)*	2.6 (CI 2.0 – 3.5)
	UUI	**Risk estimates**
No AI	21.4 (140/653)	1
Only Flatus	30.9 (157/508)*	1.6 (CI 1.3 – 2.1)
Only LSI	40.5 (17/42)*	2.5 (CI 1.3 – 4.7)
Only SSI	33.3 (3/9)*	1.8 (CI .4 – 7.4)
Flatus + LSI	56.9 (58/102)	4.8 (CI 3.1 – 7.5)
Flatus + SSI	47.1 (8/17)	3.3 (CI 1.2 – 8.6)
LSI + SSI	60.0 (3/5)	5.5 (CI .9 – 33.2)
Flatus + SSI + LSI	61.5 (8/13)	5.8 (CI 1.8 – 18.2)
	SUI	**Risk estimates**
No AI	45.6 (297/652)	1
Flatus	62.5 (318/509)*	2.0 (CI 1.6 – 2.5)
LSI	56.1 (23/41)*	1.5 (CI .9 – 2.9)
SSI	33.3 (3/9)	.6 (CI . 2 – 2.4)
Flatus + LSI	68.9 (71/103)	2.6 (CI 1.7 – 4.1)
Flat + SSI	58.8 (10/17)	1.7 (CI .6 – 4.5)
LSI + SSI	60.0 (3/5)	1.8 (CI .3 – 10.8)
Flatus + SSI + LSI	57.1 (8/14)	1.6 (CI . 6 – 4.7)

The association between group of UI and each of the AI components Flatus, LSI and SSI was assessed by logistic regression analyses. The same was done for the association between group of AI and the presence or absence of urge UI respectively stress UI as outcome variable.) Associations were expressed as odds ratios.(p <.005)*

Table VI Quality of life, scored by EuroQol-5D(EQ-5D) and visual analogue scale (VAS)

		n=1,323	n=1,375
		EQ-5D	**VAS score**
Continent	mean	.8595	812.207
	median	.8500	850.000
	St.Dev	.17773	1.307.154
UI	mean	.8246	789.137
	median	.7960	800.000
	St.Dev	.17755	1.405.530
FI	mean	.8087	778.571
	median	.7960	850.000
	St.Dev	.21020	1.524.112
DI	mean	.7221	723.944
	median	**.7790***	**750.000***
	St.Dev	.23530	1.627.248
Total	mean	.8266	790.618
	median	.7960	800.000
	St.Dev	.18936	1.420.221

*) *significant (p < .000)*

Discussion

In our general female study population, 10.3% of the women reported DI, while 35.4% reported DIF. Differences were found in variables such as BMI, postmenopausal status, smoking behaviour, surgical history and a family history of a mother with UI, between the incontinent women (UI, FI and DI) and the continent women. This is in line with the results of other studies.[15-16] However, it should be realized that the differences in BMI are not clinically relevant, but only an arithmetical outcome.

Urinary incontinence

In our study, 25.9% reported that they were continent; 6.1% reported UUI alone, 30.5% reported SUI alone and 23.2% reported MUI. In the study by MacLennan [1] on an Australian general population, the scores were lower (2.9%, 20.8% and 11.6%, respectively). This can be explained by our different choice of method to analyse the isolated symptoms (e.g. SUI alone). In addition, differences can be explained on the basis of age (15-65 years in the MacLennan study compared to 45-85 years in the current study). In agreement with other studies, we found that the majority of women with UI were only 'a little' or 'moderately' bothered by it. For instance, in the group of 412

women who reported SUI, only 149 were bothered 'quite a lot' or 'a lot'. There was no significant difference in bother score between the UUI group and the SUI group, which is comparible with the results of a recent study by Dooley et al.[17] who also studied SUI and UUI as solitary symptoms.

The lack of differences between the different parity groups can be explained by the statistical test we used. Only the relation between the different parities was tested, not the contrasts between parity groups.

Anal incontinence

In the literature, prevalence rates of AI vary widely depending on the age and characteristics of the study population. Our rates of 3.5% for SSI and 12.3% for LSI are consistent with the data from other studies on AI in a general population.[16-17] Data on the prevalence of FlI are scarce. In our study, the FlI was 39%, which is comparable with the few results mentioned by other studies.[8,17] Compared to SUI and FlI, FI caused increased bother irrespective of whether it was SSI or LSI. This is hardly surprising given the nature of the symptoms. AI prevalence was higher in the parous women than in the nulliparous women, although not significantly.

Double incontinence

The overall prevalence of double incontinence in its broadest sense, i.e. AI (including FlI) and UI (DIF) was 35.3%. When FlI was excluded, the prevalence of DI decreased to 7.7%. Prevalences increased with age, which can be explained by the normal aging process with loss of mobility, dexterity, fascia, connective tissue and striated muscle. Similar results were reported in another Dutch study.[10] Table V shows the ORs for UI and FI, with a 4-fold risk of LSI when UUI was present (4.3, 95% CI 2.4-7.9).

Different theories have been put forward about integral factors that lead to strong co-morbidity between DI and UUI. One of the theories is the presence of crossed reflexes between the urethra, bladder and pelvic floor, which have been found in animal studies.[18-19] Crossed vesico-urethro-anal reflexes between the urethra and the anal sphincter were also described by Shafik [19] and Bouvier and Grimaud.[20] Using EMG, they demonstrated that the passage of urine through the urethra, or stimulation of the vesical neck, produced increase activity in the external anal sphincter, which presumably indicated external anal sphincter contraction. It is well-known that sacral neuromodulation, started as a therapy for UUI, has positive effects on FI.[21] This therapy has also proven to be effective in patients with DI if they have UUI, but not SUI.[22] We hypothesize that disturbance in one part of the vesico-urethral-anal reflex automatically influences another part of the reflex, but realize that this is merely speculations and further research will

be necessary. Furthermore, in the literature, a common central or peripheral disorder of the smooth muscle has also been suggested as a cause of UUI and FI.[4,7-8,23]

The underlying mechanisms of co-morbidity between SUI and DI are different from those of UUI and AI, because in SUI, it is very likely that the striated muscles and/or nerve supply are affected. Dysfunction of the striated sphincter complex and/or damage to the nerve supply can lead to improper function of the anal sphincter complex, as well as co-morbidity with AI, specifically in women with anal sphincter damage after obstetrical trauma.[24] However, in our study the OR for experiencing SUI almost seemed protective against SSI (0.6) and it was not as high as we expected. We hypothesize that women with SUI have greater awareness of their pelvic floor musculature (PFM) and will contract their muscles more consciously to avoid leakage. In the literature, the efficacy of PFM training in SUI is well-documented [25] and it has received a lot of public attention that has led to increased awareness of the PFM in these women and the positive results of keeping the muscles in good condition.

A relevant factor in DI is the inability to resist any increase in bladder and rectal pressures. This can result in an episode of urge urinary and/or anal incontinence and this occurs more frequently in women. These women also seem to be more prone to urinary irritative symptoms. The association between irritative bladder symptoms (overactive bladder and interstitial cystitis) and urge anal incontinence in women with AI is of extreme interest, because it supports the view that a common visceral mobility disorder plays a role in DI.[23]

Women with incontinence are often reluctant to seek treatment at an early stage and they do not easily take the initiative to talk about any form of AI. We therefore recommend that when clinicians take the history of women with UUI or MUI, they include questions about the co-existence of any form of AI. This is important because if co-morbidity is present, optimal treatment must focus on the AI and UI.

Comparison between premenopausal and postmenopausal women only revealed a significant difference in FlI ($p < .001$). In our opinion, age played an important role in this mechanism.

Strengths and limitations

As far as we know, this study is the first to provide very detailed data on the prevalence of UI and FI in a general female population. Data were collected not only on the prevalence of the various types of incontinence, but also on the impact and frequency of the symptoms. We chose the setting of a small Dutch town and invited all the older women to participate. Although our re-

sults are not necessarily representative of the entire multicultural Dutch population (by coincidence we studied an almost entirely white population) they provide valuable information on a racially homogeneous group of women.

A limitation of our study was the chosen age group, which caused limited information in the general population. In future research the younger women should be included to gain more information on a wider range of ages. Another limitation is that we used the EQ-5D which is a generic questionnaire. We did not ask explicitely for co-morbidity what especially would be interesting in the older age groups. In future studies these items should be included. We also did not ask explicitely for the home situation. Especially for the older women a bias can be present if they are living in a care home. Another important limitation of our study was the lack of objective clinical validation of the symptoms, which may have influenced the real prevalences. Misbalance in the answers was found especially regarding frequency and bother. Sometimes a little bother was reported by women in the absence of UI. As only a limited number of women were using HRT, we did not expect any significant distortion of data after excluding these women from the analysis.

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References

1. Maclennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. Bjog 2000;107:1460-70.
2. Goode PS, Burgio KL, Halli AD, Jones RW, Richter HE, Redden DT, Baker PS, Allman RM. Prevalence and correlates of fecal incontinence in community-dwelling older adults. J Am Geriatr Soc 2005;53(4):629-635.
3. Van Der Vaart CH, De Leeuw JR, Roovers JP, Heintz AP. [The influence of urinary incontinence on quality of life of community-dwelling, 45-70 year old Dutch women] De invloed van urine-incontinentie op de kwaliteit van leven bij thuiswonende Nederlandse vrouwen van 45-70 jaar. Ned Tijdschr Geneeskd 2002;144:894-7.
4. Lacima G, Pera M. Combined fecal and urinary incontinence: an update. Curr Opin Obstet Gynecol 2003;15(5):405-410.
5. Kapoor DS, Thakar R, Sultan AH. Combined urinary and faecal incontinence. Int Urogynaecol J Pelvic floor dysfunct 2005. 16(4):321-8
6. Meschia M, Buonaguidi A, Pifarotti P, Somigliana E, Spennacchio M, Amicarelli F. Prevalence of anal incontinence in women with symptoms of urinary incontinence and genital prolapse. Obstet Gynecol 2002;100(4):719-723.

7. Khullar V, Damiano R, Toozs-Hobson P, Cardozo L. Prevalence of faecal incontinence among women with urinary incontinence. Br J Obstet Gynaecol 1998;105:1211-3.
8. Manning J, Eyers AA, Korda A, Benness C, Solomon MJ. Is there an association between fecal incontinence and lower urinary dysfunction? Dis Colon Rectum 2001;44(6):790-798.
9. Thomas TM, Egan M, Walgrove A, Meade TW. The prevalence of faecal and double incontinence. Community Med 1994:6(3):216-220.
10. Teunissen TA, Lagro-Janssen AL, van den Bosch WJ, van den Hoogen HJ. Prevalence of urinary, fecal and double incontinence in the elderly living at home. Int Urogynecol J Pelvic Floor Dysfunct 2004;15(1):10-13; discussion 13.
11. Edwards, P, Roberts, I, Clarke, M, Diguiseppi, C, Pratap, S, Wentz, R, et al. Increasing response rates to postal questionnaires: systematic review. Bmj 2002;324:1183.
12. Van Brummen, HJ, Bruinse, HW, Van De Pol, G, Heintz AP, Van Der Vaart CH. Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. Int Urogynecol J Pelvic Floor Dysfunct 2006;17:224-30.
13. Essink-Bot ML, de Haes JCJM. Kwaliteit van leven in medisch onderzoek. Een inleiding. Quality of life in medical research. An introduction. Amsterdam: Amsterdam University Press, 1996.
14. Hunskaar S, Burgio K, Clark A, Lapitan MC, Neslon R, Sillén U et al., Epidemiology of urinary and faecal incontinence and pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, International Continence Society, Société International d'Úrology, eds. Incontinence, third annual consultation on incontinence, vol 1, Basics and evaluation, Plymouth, England: Health Publications Ltd. 2005;255-312. Report of ICI.
15. Danforth KN, Townsend MK, Lifford K, Curhan GC, Resnick NM, Grodstein F. Risk factors for urinary incontinence among middle-aged women. Am J Obstet Gynecol 2006;194(2):339-345.
16. Shamliyan T, Wyman J, Bliss DZ, Kane RL, Wilt TJ. Prevention of urinary and fecal incontinence in adults. Evid Rep Technol Assess (Full Rep)2007;(161):1-379.
17. Dooley Y, Lowenstein L, Kenton K, FitzGerald M, Brubaker L. Mixed incontinence is more bothersome than pure incontinence subtypes. Int Urogynecol J Pelvic Floor Dysfunct 2008;19(10):1359-1362.
18. Shafik A. Re: Cough anal reflex: strict relationship between intravesical pressure and pelvic floor muscle electromyographic activity during cough. Urodynamic and electrophysiological study. J Urol 2005;174(4 Pt 1):1502-1503; author reply 1503.
19. Shafik A, Shafik I, El-Sibai O. Effect of rectal distension on vesical motor activity in humans: the identification of the recto-vesicourethral reflex. J Spinal Cord Med 2007;30(1):36-39.
20. Bouvier M, Grimaud JC. Neuronally mediated interactions between urinary bladder and internal anal sphincter motility in the cat. J Physiol 1984;346:461-469.

21. Tjandra JJ, Chan MK, Yeh CH, Murray-Green C. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. Dis Colon Rectum 2008;51(5):494-502.
22. Leroi AM, Michot F, Grise P, Denis P. Effect of sacral nerve stimulation in patients with fecal and urinary incontinence. Dis Colon Rectum 2001;44(6):779-789.
23. Soligo M, Salvatore S, Milani R, Lalia M, Malberti S, Digesu GA, Mariani S. Double incontinence in urogynecologic practice: a new insight. Am J Obstet Gynecol 2003;189(2):438-443.
24. Sultan AH, Monga AK. Anal and urinary incontinence in women with obstetric anal sphincter rupture. Br J Obstet Gynaecol 1997;104(6):754-755.
25. Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment for urinary incontinence in women. A Cochrane systematic review. Eur J Phys Rehabil Med 2008; Mar 44(1)47-63.

Chapter 8

Vaginal noise: prevalence, bother and risk factors in a general female population aged 45-85 years

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Abstract

Introduction Vaginal noise (VN) is a symptom of pelvic floor (PF) dysfunction and has been described in a few studies. No other risk factors have been described, besides parity and pelvic organ prolapse (POP). Underlying mechanisms of VN are unclear. Aims of this study were to describe prevalence, bother and relation between VN and PF (muscle)(dys)function.
Methods A cross-sectional study was performed on a general population of 2,921 women(aged 45-85 years). Questionnaires were filled in by 1,397 women and 800 were selected at random to undergo vaginal examination for POP Quantification and PF muscle function assessment. Chi-square tests, student's *t*-test and multivariate logistic regression were performed ($P < .05$).
Results Response rate was 62.7%. Prevalence of VN was 12.8%; 72.1% reported only a little bother. Odds ratios for parity and solid stool were high.
Conclusions VN was strongly related to many symptoms of pelvic floor dysfunction, but it was only causing a little bother.

Keywords pelvic floor dysfunction; pelvic floor musculature; risk factors; vaginal noise

Summary
Prevalence of VN was 12.8%. Odds ratios were highest on the risk factors solid stool incontinence and parity.

Introduction

Many older women have symptoms of pelvic floor dysfunction that can be a cause of social distress and loss of quality of life due to taboo and shame about these conditions.[1-5] Frequently described symptoms of pelvic floor dysfunction include vaginal bulging, micturition problems (e.g. urinary incontinence (UI) and dysfunctional voiding), defaecation symptoms (e.g. faecal incontinence and obstruction) as well as vaginal and sexual dysfunction (e.g. dyspareunia).[1,3-8] In our experience, it is not uncommon for women to experience VN, especially during posture changes and sexual intercourse. VN is typically described as a very weak sound, very similar to, but far weaker than, anal flatus.

Recently, the symptom of VN has been described in a group of six women who visited a tertiary care pelvic floor referral centre.[9] No prevalence data were given. The results showed that VN was not associated with pelvic floor muscle (PFM) dysfunction, because PFM training was ineffective for VN. A few studies have emphasized that PFM contraction in response to vaginal or rectal distension may cause VN. However, this does not explain the mechanism of air being sucked into the vagina.[10-12] The underlying mechanism of VN is still unknown. It is possible that air becomes trapped in the posterior fornix and that during sudden movements it is released and produces the typical noise.[13]

Aims of the present study were (1) to determine the prevalence of VN, (2) to measure the amount of bother caused by this symptom, (3) to search for possible risk factors, such as symptoms of PFM (dys)function (muscle strength, endurance, urethral lift and reflex contraction), (4) to document the severity of pelvic organ prolapse (POP); stages 0-4 according to the pelvic organ prolapse quantification (POPQ) and the 9-point notation of the POPQ) and (5) to explore sexual activity (yes/no) and symptoms of PF in a general population of women aged 45-85 years.

Material and Methods

This study is part of a large cross-sectional study that was performed on a general population of mostly white Dutch women aged 45 to 85 years. Figure 1 presents the flowchart of the study.

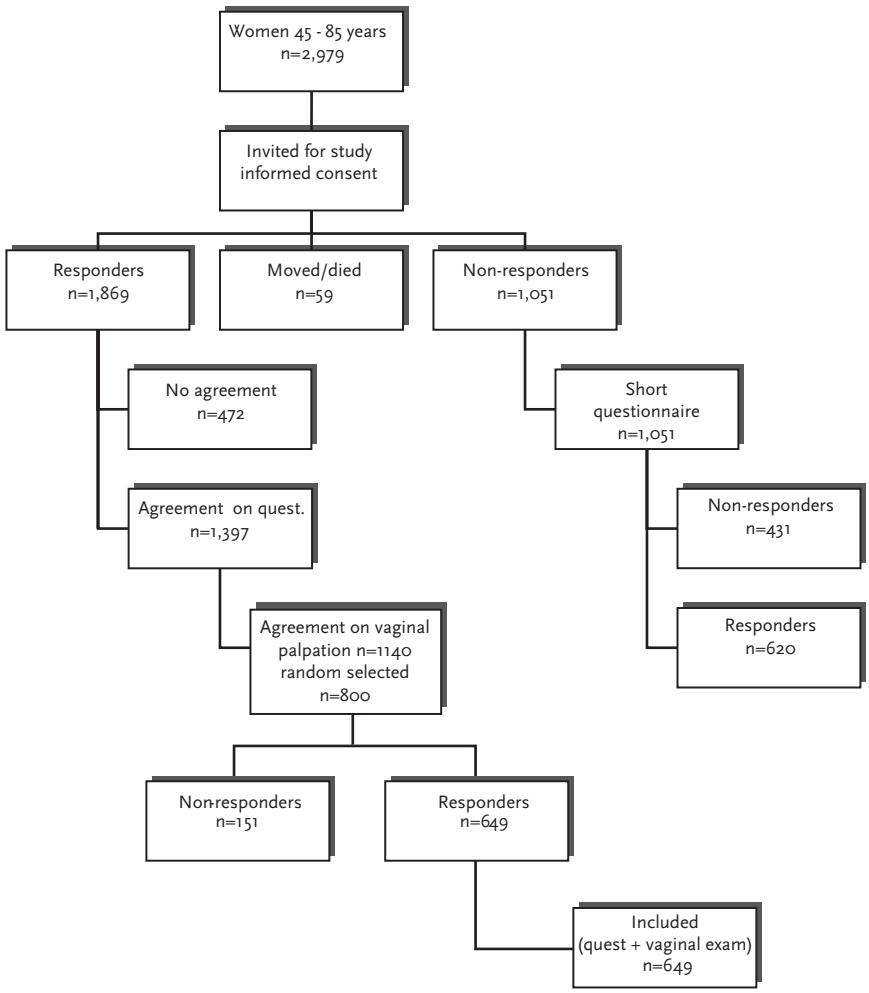


Figure 1 Flowchart of the study

The total population of women aged 45-85 years (n=2,921 out of 16,000 citizens) registered on the patient lists of eight out of the nine general practitioners in the town of Brielle (near Rotterdam, the Netherlands) were approached to participate in the present study. Names and addresses were obtained from the general practitioners. As all the inhabitants are obliged to register with a general practitioner, the study population included 95% of all the women in this age range. The women were sent information about the study and could enrol by filling out an informed consent form. They were offered three options: to sign a refusal form, to fill out the questionnaire only or to fill out the questionnaire and undergo vaginal examination.

All the women were asked to complete a self-report questionnaire. Non-responders received a reminder eight weeks later that contained the same questionnaire. Data were collected anonymously. To avoid selection bias, non-responders were invited to complete a short questionnaire that comprised five questions about: age, parity, presence of urinary stress incontinence (yes/no), faecal incontinence (yes/no) and feeling vaginal bulging (yes/no). To encourage a high response to the questionnaire, we used envelopes with the name and logo of the Erasmus University, coloured paper and stamped-addressed return envelopes.[14] Each reminder included the same questionnaire.

Self-report postal questionnaire

The questionnaire used in this study combined several validated Dutch versions of pelvic floor questionnaires, such as the Urogenital Distress Inventory (UDI) [15] and the Defaecation Distress Inventory (DDI).[16] In addition, subjects were asked about ethnicity, parity, vaginal bulging, incontinence, family history, menopausal state, hormone replacement therapy (HRT), previous pelvic floor surgery, educational level, smoking, heavy physical work currently or in the past. One question on VN was included in the questionnaire: 'Do you ever experience VN, for example when changing from a sitting to a standing position or vice versa?' If the answer was yes, the further enquiry 'How much are you bothered by this?' could be answered on a 4-point Likert scale: 'not at all', 'a little', 'quite a lot' or 'a lot'.

Vaginal examination

From all the participants who gave informed consent to undergo vaginal examination (n=1,140), eight hundred women were randomly selected for POPQ measurement and PFM function testing. (All the response forms were coded with a number that identified the woman's age and then a research assistant selected the study sample at random).). The POPQ was introduced by the International Continence Society (ICS). It has become widely accepted and has proven to be valid [17] and reliable.[18] PFM was tested for strength (absent, weak, normal, strong), endurance (0-10 seconds), the ability to achieve urethral lift (yes/no) and an effective reflex contraction during coughing (that resulted in inward perineal movement, yes/no).

One gynaecologist and one physiotherapist performed the vaginal examinations. They practiced the vaginal examination protocol until they reached agreement about the test and registration scores. This process was performed at the Pelvic Floor Centre of the Erasmus MC in Rotterdam. POPQ measurements were carried out in conformity with the ICS standardisation report.[17]

After each vaginal examination, all the details were entered into the three-by-three POPQ grid. Four PFM items were tested according to the new terminology.[19-20] The two examiners were blinded to the results of the questionnaire. All the vaginal examinations were performed in the second half of the day, between 14.00 and 21.00 hours. The women were asked to empty their bladder before the examination.

Participants were assigned to one of the five ordinal stages of prolapse (0 – 4) in accordance with the POPQ grading system. All the methods, definitions and descriptions were in line with the ICS.[17]

Statistical analysis

The analyses were performed using the Statistical Package for the Social Sciences (SPSS Inc) 15.0. To determine differences between the women with complaints of VN and those women without, Chi-square tests were used on categorical items and student's *t*-test on continuous items. To determine potential risk factors for VN, multivariate logistic regression was used with backward stepwise elimination of variables at the level $P < .05$. Results were obtained as odds ratios (ORs) with 95% confidence intervals. Associations between the 9-point notation of the POPQ and VN were tested using multivariate logistic regression. The Medical Ethics Research Committee (METC) of the Erasmus MC in Rotterdam, the Netherlands, approved this study.

Results

The response rate to the questionnaire was 62.7% (1,869/2,979). In the group of 1,869 responders, 472 women refused to participate, 1,397 agreed to fill out the large questionnaire and 1,140 agreed to fill out the questionnaire and undergo vaginal examination. In the non-responder group, 59% filled out and returned the short questionnaire (620/1,051). There were no significant differences between the non-responders group and the responders group between the five asked items. Vaginal bulging was reported by 6.7% (n=41) compared to 9.8% in the group of participants (135/1,397). In the group who consented to undergo vaginal examination (n=1,140), 800 women were selected at random and sent an invitation; 649 women complied (81.1%).

Table I presents the baseline characteristics.

Table I Baseline characteristics of the total study population, those who underwent a physical examination and the non-responder group, expressed as numbers (%) and means

Characteristics of the total study population	Questionnaire Total n=1,397	Physical exam total n=649	Study group vaginal noise n=175 (12.8)
Mean age (range 45-84 yrs)	**58.0 (SD ± 9.2)**	**58.3**	**56.5 (SD ± 8.11)**
Mean BMI	n=1,364	n=634	n=173
	25.6 (SD ± 3.9)	**25.6 (SD ± 3.7)**	**25.8 (SD ± 3.8)**
Race	n=1,372	n=640	n=174
White	1,351 (96.7)	632 (97.4)	169 (97.1)
Non-white	20 (1.4)	8 (1.2)	5 (2.9)
	n=1,340	n=639	n=176
Median parity	**2**	**2**	2
0	120 (8.6)	49 (7.6)	6 (3.4)
1	215 (15.4)	86 (13.3)	21 (11.9)
2	675 (48.3)	321 (49.5)	93 (52.8)
≥3	387 (27.7)	183 (28.2)	56 (31.8)
Menopausal status	n=1,383	n=645	n=174
(Pre)menopausal	374 (26.8)	167 (25.7)	56 (32.2)
Postmenopausal	1,009 (72.2)	478 (73.7)	118 (67.8)
Surgical history	n=1,384	n=645	n=173
Prolapse	103 (7.4)	54 (8.3)	17 (9.8)
	n=1,382	n=643	n=171
Incontinence	47 (3.4)	24 (3.7)	11 (6.4)
	n=1,383	n=643	n=174
Hysterectomy	234 (16.8)	109 (16.8)	32 (18.4)
Family history	n=985	n=441	n=132
Mother POP	359 (25.7)	161 (36.5)	55 (41.7)
	n=870	n=398	n=117
Mother UI	258 (29.7)	122 (30.6)	54 (46.2)
Heavy physical work	n=1,381	n=642	n=174
Current	269 (19.3)	130 (20)	30 (17.2)
	n=1,384	n=645	n=175
Ever	619 (44.3)	293 (45.1)	82 (46.9)

There were positive responses to the question on VN in 12.8% of the women (176/1,378) (19 responses on VN were missing). The vast majority (96%) (n=169/176) were not at all bothered by it, or only a little. In 43 women, the amount of bother was unknown (see table II). There were no significant dif-

ferences in VN between the sexually active women (13.3%) and the sexually inactive women (12.2%).

Table II Number of women with complaints of vaginal noise and the level of bother. 1 evaluation is missing

Bother unknown	**1**[*)]
Not at all	42
A little	127
Moderate	5
Very much	1
Total	175 (12.8%)

*) *Due to missing data, percentages do not always correspond with the total group*

Table III Relation between POPQ stage and the presence of the symptom of vaginal noise in the subgroup who underwent vaginal examination (Chi-square for trend p=.055) 14 missing. (6 POPQ incomplete, 8 VN question not answered)

	Vaginal noise n (%)	Total n
Stage 0	18 (11.4)	158
Stage 1	26 (11.2)	233
Stage 2	33 (15.7)	210
Stage 3	8 (25.8)	31
Stage 4	0	3
Total	85 (13.4)	635[*)]

*) *Due to missing data percentages do not always correspond with the total group.*

Table III shows the (non-significant) relation between the presence of VN and the POPQ stage in the women who underwent vaginal examination (n=635, n=14 evaluations were missing). Analysis of the detailed 9-point notation in the POPQ grid showed that only the lowest point of the posterior vaginal wall (point Bp) was significantly related to VN (p=.003). Furthermore, no significant differences were found in the strength and endurance of the pelvic floor musculature, the ability to achieve urethral lift and an effective reflex contraction during coughing that resulted in inward movement of the perineum between the VN positive and the VN negative women (data not shown).

Table IV Prevalence of the risk factors in relation to vaginal noise of the total study group

	vaginal noise	
	no	yes
	n=1,177	n=171
urge urinary incontinence	321 (27.3)	74 (43.3)
	n=1,176	n=173
stress urinary incontinence	609 (51.8)	119 (68.8)
	n=1,193	n=172
vaginal bulging	123 (10.3)	36 (20.9)
	n=1,195	n=174
digital defecation	89 (7.4)	24 (13.8)
	n=1,194	n=173
liquid stool loss	128 (10.7)	38 (22)
	n=1,196	n=174
solid stool loss	31 (2.6)	16 (9.2)

Table V Results of the univariate and multivariate logistic regression (p <.05)

	univariate analysis			multivariate analysis		
	OR	95 % CI		OR	95 % CI	
age	.98	.96	.99	.97	.94	.99
parity	**2.79**	1.21	6.45	**4.51**	1.69	12.09
bmi	1.02	.98	1.06	*	*	*
menopause	.75	.54	1.06	*	*	*
urge urinary incontinence	**2.03**	1.47	2.83	*	*	*
stress urinary incontinence	**2.05**	1.46	2.99	**1.63**	1.11	2.37
vaginal bulging	**2.30**	1.53	3.48	**2.36**	1.50	3.72
digital defaecation	**1.99**	1.23	3.22	**1.87**	1.08	3.25
incontinence of liquid faeces	**2.34**	1.57	3.51	**2.07**	1.31	3.26
incontinence of solid faeces	**3.81**	2.04	7.12	**4.55**	2.22	9.32
incontinence of flatus	**2.92**	2.07	4.13	**2.34**	1.59	3.42

**) no significant association in multivariate analysis could be demonstrated.*

Table IV shows the prevalence of the risk factors in relation to vaginal noise, used for the further analysis. Table V shows the results of the univariate and multivariate analyses, carried out to identify risk factors for symptoms of pelvic floor dysfunction associated with VN. The univariate analysis revealed significant risk estimates, especially on parity, urinary urge and stress incontinence, vaginal bulging, manual evacuation of faeces, flatal incontinence, solid stool and fluid stool incontinence, with the highest risk estimate on solid stool incontinence (OR 3.81 95% CI 2.04-7.12). In the multivariate analy-

sis, most of the variables remained significant, with surprisingly high risk estimates on parity and solid stool incontinence of 4.51 (95% CI 1.69-12.09) and 4.55 (95% CI 2.22-9.32), respectively.

Discussion

VN is a well-known symptom to most gynaecologists and pelvic floor physiotherapists, but little is known about the prevalence and possible risk factors. Data from this study revealed that this symptom is not uncommon. Roughly one out of the eight women in a general population had the symptom of VN (12.8%). This is in contrast with the data presented by Krissi et al., who did not find any cases of VN in 250 women who visited a urogynaecology clinic (2003). In a recently published article, Krissi et al. [9] claimed to be the first authors to describe "vaginal wind". However, Attapattu was the first to describe the symptom of VN in 1995, for which he coined the phrase 'Garrulitas vulvae' (chattering vulva).[21] In our opinion, VN is a better term than vaginal wind, because the exact mechanism is unclear and "noise" does not connote to anal flatus.

The bother caused by VN was modest. Only six out of the 175 (3.4%) women reported being moderately or very bothered by it. This seems to disagree with Krissi et al. [9] who suggested that VN is an extremely embarrassing problem, although they did not test for the bother of VN. The low bother score reported by the vast majority of women might partly explain the lack of attention that the symptom has received in the literature.

We were unable to find an association with sexual activity, which suggests that the symptom of VN does not influence sexual activity. In our analysis to explore the relation to the POP-Q score, the prevalence of VN in POP stages 3 and 4 was twice as high as in the lower stages, although this did not reach significance possibly due to the small numbers with the higher stages. This is in line with the findings in the case report published by Krissi et al.[9]

As pelvic floor physiotherapy was not effective in the study by Krissi et al., we also tested the association between PFM function and VN. No significant differences could be demonstrated between the symptomatic and asymptomatic women, which might explain the disappointing results of PFM training in women with VN.

Risk factors

Many symptoms of pelvic floor dysfunction proved to be significant risk factors for VN: flatal incontinence, fluid stool and solid stool (anal incontinence) had high risk estimates. In the multivariate analysis, solid stool incontinence

had the highest risk estimates (OR 4.55, 95% CI 2.22 – 9.32). However, the confidence interval was wide, which influenced the strength of the OR. It is well-known that anal incontinence is extremely embarrassing and has a strongly negative influence on quality of life.[22-23] This might also explain the low bother of VN if the women were comparing it to anal incontinence. It is difficult to formulate an explanation for VN associated with solid stool incontinence, but we assume that diminished function of the internal anal sphincter (responsible for passive closure of the rectum) can play a role, because PFMF was not associated with VN. Parity has also been hypothesized to be the major risk factor.[9] Our univariate and multivariate analyses reinforced the importance of the risk factor parity (OR 4.51).

Underlying mechanism of VN

In 1996, Nokes et al. reported the existence of intra-vaginal air in 11% of their (normal) radiology patients, but nothing was mentioned about the escape of vaginal air.[24] Analysis of the first notation of the POPQ in the 9-point grid revealed that the Bp point was of significant importance, which might reflect anatomical changes that partly explain the development of VN. We hypothesize that a significantly high score on the posterior vaginal wall (point Bp) means that the vagina remains closed during changes of position from sitting to standing, or vice versa.

Limitations

This study had some limitations. The questionnaire was long and not all women can be expected to want to undergo the burden of vaginal examination. Therefore selection bias may have occurred. The women may have opted to participate due to their symptoms, which would have overestimated the prevalence and bother of VN.

Furthermore, especially in the bother question a 4-point Likert scale was used which is not sensitive. There may be a significant proportion of women who fall in between the 'a little' and 'moderate' category and this scale does not allow proper differentiation between the subjects. If we had used a 10-point system or a visual analogue scale our results may have been very different.

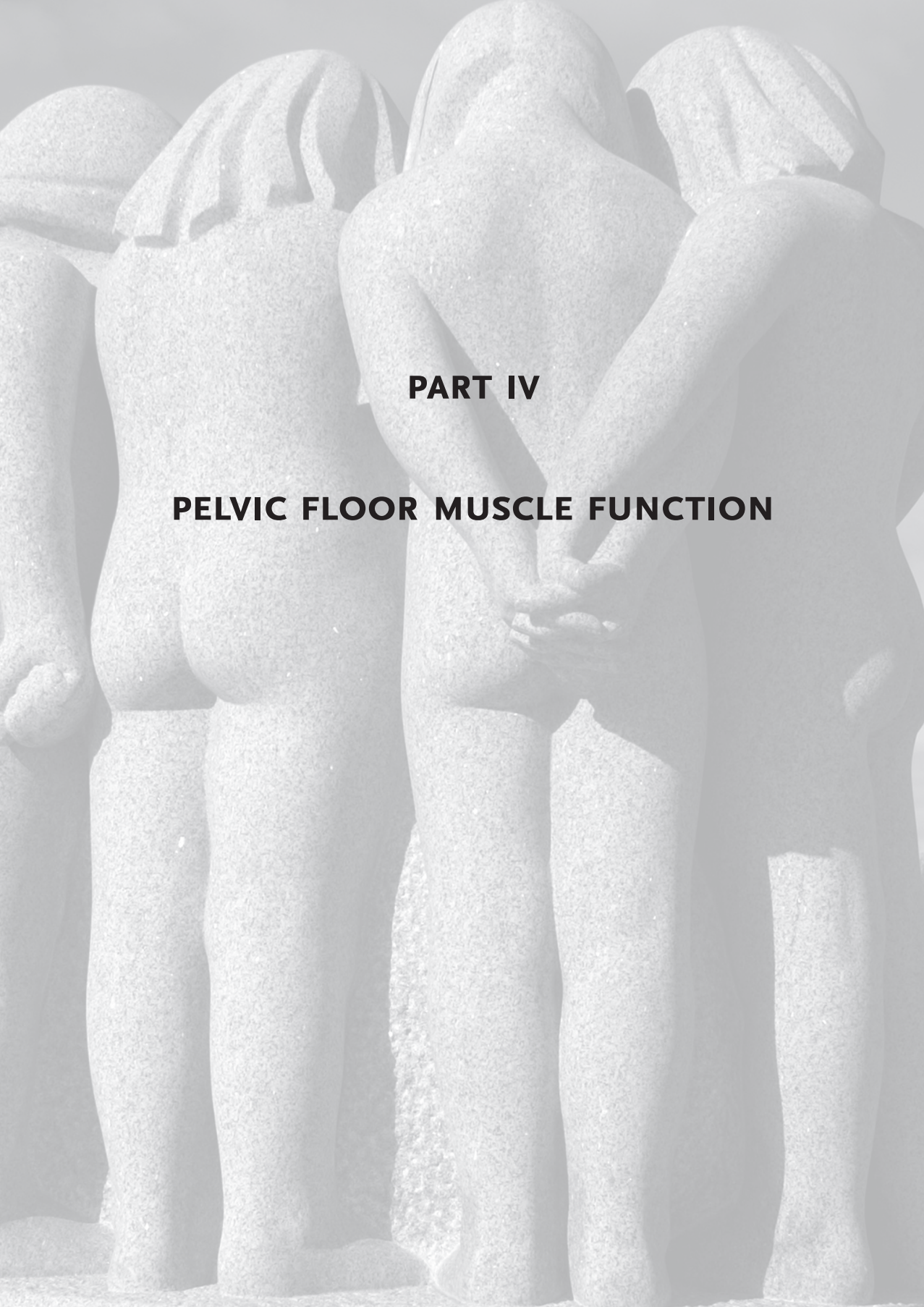
Conclusion

VN was not uncommon in our studied Dutch women aged 45-85 years. It was strongly related to many symptoms of pelvic floor dysfunction, with the highest risk estimates on parity and solid stool incontinence. Although VN was found to have a low bother score, it can be very embarrassing to some women and therefore deserves more attention than it has received until now. Based on the results of our study, it is unclear which therapy is most suitable for this symptom.

References

1. Eva, UF, Gun, W, Preben, K (2003) Prevalence of urinary and fecal incontinence and symptoms of genital prolapse in women. Acta Obstet Gynecol Scand 82:280-6.
2. Uustal Fornell, E, Wingren, G, Kjolhede, P (2004) Factors associated with pelvic floor dysfunction with emphasis on urinary and fecal incontinence and genital prolapse: an epidemiological study. Acta Obstet Gynecol Scand 83:383-9.
3. Maclennan AH, Taylor AW, Wilson DH, Wilson, D (2000) The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. Bjog 107:1460-70.
4. Swift, S, Woodman, P, O'Boyle, A, Kahn, M, Valley, M, Bland, D, et al. (2005) Pelvic Organ Support Study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. Am J Obstet Gynecol 192:795-806.
5. Nygaard, I, Bradley, C, Brandt, D (2004) Pelvic organ prolapse in older women: prevalence and risk factors. Obstet Gynecol 104:489-97.
6. Swift SE, Pound T, Dias JK (2001) Case-control study of etiologic factors in the development of severe pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct 12:187-92.
7. Kahn MA, Stanton SL (1997) Posterior colporrhaphy: its effects on bowel and sexual function. Br J Obstet Gynaecol Jan;104(1):82-6.
8. Nichols CM, Ramakrishnan V, Gill EJ, Hurt WG (2005) Anal incontinence in women with and those without pelvic floor disorders. Obstet Gynecol Dec;106(6):1266-71.
9. Krissi H. Medina C, Stanton SL (2003) Vaginal wind – a new pelvic symptom Int Urogynaecol J 14:399-402.
10. Filipini DL, Dubrovsky B (1991) Pelvic floor muscles response to graded rectal distension and cutaneous stimulation. Dig Dis Sci 36:1761–1767.
11. Shafik A (1993) The recto-levator reflex: the distension of a new reflex and its clinical application. Preliminary report. Clin Physiol Biochem 10:13–17.
12. Shafik A (1995) Vagino-levator reflex: description of a reflex and its role in sexual performance. Eur J Obstet Gynecol Reprod Biol 60:161–164.
13. Hadar H, Kornreich L, Heifettz M, Herskovitz P, Horev G (1991) Air in vagina. Indicator of intrapelvic pathology on CT. Acta Radiol 32:170-3.

14. Edwards P, Roberts I, Clarke M, Diguiseppi C, Pratap S, Wentz R, et al. (2002) Increasing response rates to postal questionnaires: systematic review. BMI 324:1183.
15. Van Der Vaart, CH, De Leeuw, JR, Roovers, JP, Heintz, AP (2000) [The influence of urinary incontinence on quality of life of community-dwelling, 45-70 year old Dutch women] De invloed van urine-incontinentie op de kwaliteit van leven bij thuiswonende Nederlandse vrouwen van 45-70 jaar. Ned Tijdschr Geneeskunde 144:894-7.
16. Van Brummen, HI, Bruinse HW, Van De Pol G, Heintz AP, Van Der Vaart CH (2006) Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. Int Urogynecol J Pelvic Floor Dysfunct17:224-30.
17. Bump RC, Mattiasson A, Bo K, Brubaker LP, Delancey JO, Klarskov P et al.(1996) The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 175:10-7.
18. Swift SE (2002) Current opinion on the classification and definition of genital tract prolapse. Curr Opin Obstet Gynecol Oct;14(5):503-7.
19. Messelink EJ, Benson T, Berghmans BJM, et al. (2005) Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn 24:374-80
20. Slieker-ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. 2008a. Face validity and reliability of the first digital assessment scheme of pelvic floor muscle function conform the new standardized terminology of the International Continence Society. Neurourol Urodyn.
21. Attapatu JA (1995) Garrulitas Vulvae, a report of six cases. J Reprod Med 40:235-6
22. Hannaway CD, Hull TL (2008) Fecal incontinence. Obstet Gynecol Clin North Am 2008 Jun; 35(2):249-69, viii.
23. Rothbarth J, Bemelman WA, Meijerink WJ, Stiggelbout AM, Zwinderman AH, Buyze-Westerweel EM et al. (2001). What is the impact of fecal incontinence on quality of life. Dis Colon Rectum Jan; 44(1):76-71.
24. Nokes SR, Martinez CR, Arrington JA, Dauito R (1986) Significance of vaginal air on computed tomography. J Comput Assist Tomogr 10:997–999.



PART IV

PELVIC FLOOR MUSCLE FUNCTION

Chapter 9

Face validity and reliability of the first digital pelvic floor muscle function assessment scheme based on the new standardized terminology of the International Continence Society

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Aims To test the face validity and reliability of a new digital pelvic floor muscle function (PFMF) assessment scheme that was designed on the basis of the recently standardized terminology of the International Continence Society.

Methods Study participants comprised 41 women, age 18-85 years. Data on age and parity were obtained. Face validity of the new assessment scheme was tested by three senior and one junior pelvic physiotherapists, using the Delphi technique. PFMF of each woman was assessed four times by three specially trained pelvic physiotherapists. Examiners were blinded to parity and other findings. To test reliability, Kappa (K) was used for the dichotomous variables and Weighted Kappa (K_w) for the items with more than two categories.

Results Mean age of the women was 41 years (SD. 10.5); 14 were nulliparous (34.1%), six primiparous (14.6%) and 21 multiparous (51.2%). The new assessment scheme showed satisfactory face validity and intra-observer reliability but low inter-observer reliability.

Conclusions The new assessment scheme based on the terminology of the ICS showed satisfactory face validity and intra-observer reliability. It can therefore be considered suitable for use in clinical practice. More detailed redefinition of the described outcome measures is necessary to improve the inter-observer reliability.

Keywords Pelvic floor musculature, pelvic floor muscle function, assessment, pelvic floor, standardization

Introduction

Reliable assessment of pelvic floor muscle function (PFMF) is of great clinical importance, because incorrect PFMF is associated with incontinence, voiding disorders, defecation disorders and dyspareunia.[1-4]

PFMF can be assessed by digital palpation [5], observation, needle EMG, pressure measurement and/or ultrasound.[6,7] Although many researchers consider that digital assessment is unreliable, it is the most commonly used technique in clinical practice.[4] In the past decade, many different digital palpation methods have been developed. The Brink score [8] and the Laycock PERFECT assessment scheme [9] are the most widely used. The Brink score employs a 4-point scale to assess the contraction pressure, vertical displacement and endurance of squeeze. The Laycock PERFECT assessment scheme uses a 6-point scale to score strength and endurance, the number of repetitions and fast contractions. Although in general the two scales have acceptable intra-observer and inter-observer reliability [10-12],Bo [10] showed that they are not suitable for research purposes.

According to the standardized terminology, recently proposed by the Pelvic Floor Clinical Assessment Group (PFCAG) of the International Continence Societey [13], an important omission is assessment of the involuntary, reflex contractions of the PFM that stabilize the pelvic floor and the urethra during an increase in intra-abdominal pressure (IAP). It has been demonstrated that effective reflex contractions play a major role in the prevention of leakage when there is an increase in IAP on the urethra.[4,14-19]

In 2004, Devreese [4] introduced a new scale that covered more PFM items and included the co-contraction of the Transverse Abdominal Muscles (TrAM). However, this scale was not based on the standardized terminology of the ICS. Therefore, we can conclude that none of the current assessment scales are based on the standardized terminology and they lack attention to involuntary contractions of the PFM. To conform with the new terminology of the ICS and to test involuntary contractions, a new digital palpation scale is required. In our study, we formulated a new digital assessment scale that was partly based on definitions of outcome measures of existing scales but incorporated the items recently proposed in the new ICS terminology. Our assessment scale was tested on face validity and reliability.

Material and Methods

The new ICS terminology has not yet been translated into clear outcome measures. Therefore, a Delphi scheme was used in five rounds to reach consensus on the contents of the new protocol. This Delphi scheme synthesizes

judgements when a uncertainty exists and utilizes the operator's common sense and the level of expertise.[20] In a literature study, our research team focused on digital PFMF assessment scales and excluded all types of equipment (such as ultra sound, manometry and ElectroMyoGram (EMG), MRI, non-English articles, surgery and pelvic organ prolapse) and the following MESH terms were used: PFMF, assessment and evaluation.

The literature search yielded 15 articles in which digital PFMF assessment had been used. These were then scored on the frequency of use in research, education and clinical practice. The research team comprised four members: two tutors in pelvic floor physiotherapy with over 12 years of experience, one senior physiotherapist with 10 years of experience in clinical work and the supervision of pelvic floor physiotherapy trainees and one junior physiotherapist without any teaching experience, but with three years of practical experience. Consensus was reached on the most relevant and frequently used PFMF assessment scales: *the Brink score* [11], *the PERFECT scheme*[9] *and the assessment method described by Devreese*.[4,14] To reach consensus on the most optimal definition of the outcome measures in the ICS terminology, the assessment schemes were discussed by the research team. Thus, the palpation protocol used in this study was based on the standardised terminology and existing definitions. Table I shows an overview of the palpation protocol used in this study. The last three columns list the currently available assessment scales which were used to refine our outcome measures as far as the standardised terminology allowed us to. They also provided insight into new and existing assessment items and different scoring methods.

Subjects

Over a 2-month period, 41 women with and without pelvic floor disorders were recruited by an advertisement in the university faculty and city of Rotterdam and from a private physiotherapy practice outside the hospital. In the advertisement, women with and without symptoms of pelvic floor disorders, like vaginal bulging, urinary or faecal incontinence, were invited to respond. No form of payment was offered. Women were eligible to participate if they were aged between 18 and 85 years, had no degenerative neurological diseases and were able to comply with the instructions (no dementia, sufficient knowledge of the Dutch language). After enrolment, the participants filled in a short questionnaire about age and parity. All the participants received basic information on PFMF and an extensive explanation of the assessment scheme. The women received a small present on completion.

Table I PFMF visual inspection and palpation protocol according the standardized terminology of the ICS (Messelink et al, 2005) plus assessment scores from Brink, Laycock and Devreese

Visual inspection	Score	Description	Laycock	Brink	Devreese
inward movement	yes	any inward movement of the perineum			1 cm
	no	no inward movement of the perineum			
	downward	any downward movement of the perineum			
co-contraction visible	yes	any co-activity of muscles other than TrAb			+ abd muscles
	no	no co-activity of other muscles was visible			
relaxation	yes	relaxation visible directly after instruction			
	no	absent, partial, hesitant or delayed relaxation			
perineal movement during coughing	yes	any downward movement of the perineum			1 cm
	no	no downward movement			
	inward	any visible inward movement of the perineum			1 cm
Incontinence	yes	any incontinence			
	no	no incontinence			
perineal movement during straining	yes	any downward movement of the perineum			
	no	no downward movement			
	inward	any inward movement of the perineum			
Palpation					
pain	yes	any pain, location left-right-anterior-posterior			
	no	no pain			
urethral lift	yes	urethral lift palpable		4 points	
	no	no urethral lift palpable			
levator closure	yes	levator closure movement palpable			
	no	no levator closure movement palpable			

symmetry left right	yes	complete symmetry between left and right						
	no	no symmetry L< R etc.						
symmetry anterior posterior	yes	complete symmetry between anterior and posterior						
	no	no symmetry ant >post etc.						
voluntary contraction	strong	strong closing and lifting cranio-anterior movement palpable				6 points	4 points	4-6 points
	normal	closing and lifting cranio-anterior movement palpable						
	weak	short contraction, no closure palpable						
	absent	no contraction						
endurance	≥10	9–7	6–4	3–1	0	10 points	4 points	
fast twitch	≥15	14–11	10–6	5–1	0	10 points		2 points
voluntary relaxation	complete	direct beyond rest level						
	partly	direct relaxation until rest level						
	absent	no relaxation palpable						
During coughing								
involuntary contraction	yes	contraction of the PFM						deep PFM
	no	no contraction of the PFM						
movement perineum	yes	any downward movement of the perineum						superficial PFM
	no	no downward movement of the perineum						
During straining								
involuntary relaxation	yes	PFM relaxation palpable						
	no	no PFM relaxation palpable						
	paradox	PFM contraction						

Assessment

The new scheme assessed voluntary and involuntary PFMF by means of observation and palpation (see table I). To reach consensus on the exact contents of the assessment scheme prior to the reliability study, three pelvic physiotherapists were trained to use the new assessment scheme by a fully qualified pelvic physiotherapist tutor. All three physiotherapists had extensive experience with pelvic floor disorders, but needed to be trained in this specific protocol (two senior physiotherapists and one junior physiotherapist).

To investigate inter-observer reliability, all the components of the assessment scheme were done separately by each of the three pelvic physiotherapists. During the assessment, the women were placed in the lithotomy position on the treatment table, with the knees flexed at 90°, moderate abduction and 35° supported hip flexion. The examiners used non-allergic gloves lubricated with water-based anti-allergen. All the women were asked to empty their bladder before the assessment.

Before starting the present large-scale assessment, the new protocol was tested by the three physiotherapists in a pilot study on six women of the included women. This showed that the terminology was still ambiguous and led to different scoring. A 6th Delphi round was necessary to enable the final fine-tuning before starting the present assessments (face validity).

The 41 women were assigned at random to the three examiners. Before the assessment, a pelvic physiotherapy student informed the participants about the assessment scheme and answered their questions. Each woman was tested in three different rooms and the examiners changed room every 10-15 minutes. In this way, each of the women was examined four times: the first three times in a random order by the three different physiotherapists and the fourth time by the physiotherapist who performed the first assessment.

All the examiners were blinded to each others' findings and to parity of the subjects. To enable the subjects to rest in between, the whole scheme of four assessments was spread over 60 minutes. After the last assessment, the examiner informed the woman about her PFMF.

Table II Detailed verbal instructions during the assessment

Assessment item	Verbal instruction
Visual inspection	
voluntary contraction	lift and squeeze your pelvic floor
	try to avoid loss of urine or flatus
Palpation	
voluntary contraction	lift and squeeze your PFM as hard as possible
endurance	make a steady but firm contraction and hold it as long as you can, while repeating 'hóld and hóld and hóld!''
fast contraction	make fast, short and strong contractions, while repeating contráct, contráct, contráct!
Reflex movement	
cough	cough forcefully
push	give a strong push

The exact instructions are shown in Table II. During the assessment, all verbal instructions were posted on the wall behind the table to ensure that the physiotherapists gave exactly the same instructions in every test. Digital assessment was performed with one finger. Palpation with two fingers was used to measure the closing movement of the levator ani. Relaxation was tested after a contraction.

Inter-observer reliability of the assessments was expressed as the percentage of agreement between two observers, calculated as the number of agreements divided by the total number of assessments. Likewise, intra-observer reliability was expressed as the percentage of agreement between the two assessments made by the same examiner. To calculate whether agreement was beyond chance, the Kappa (K) statistic was used for dichotomous variables and the Weighted Kappa (K_w) for the items with more than two categories. The criteria given by Landis and Koch [21] (Table III) were used to express the strength of the agreement. The kappa values for inter-observer agreement between three examiners were estimated by means of the Intra-Class Correlation Coefficient (ICC), which is equivalent to a quadratic ally weighted Kappa.[33]

When variables have very skewed distributions, e.e. if the vast majority of women are rated in one particularly category by two examiners, the level of agreement will be high, but as a large part of that agreement can be attributed to chance alone, the Kappa value actually may be very low.[22] All the statistical analyses were performed with SPSS package 11.5.

The study was approved by the Medical Ethics Research Committee (METC) of the Erasmus MC in Rotterdam, the Netherlands. All subjects gave informed consent before they entered the study.

Table III Criteria for the interpretation of Cohen's Kappa following Landis and Koch [21]

Value of Kappa	Interpretation
< 0	Poor
0.00 – 0.20	Slight
0.21 – 0.40	Fair
0.41 – 0.60	Moderate
0.61 – 0.80	Substantial
0.81 – 1.00	Almost perfect

Results

A total of 41 women were examined. (mean age of 41 years (SD 10.5), range from 22 to 63 years). Age did not have a normal distribution, as assessed by the Kolmogorov-Smirnov test: P .025. Data on parity status showed that 14 women were nulliparous (34.1%), 6 primiparous (14.6%) and 21 multiparous (51.2%). Table IV presents the overall agreement and K_w of the inter-observer variability of all three examiners, together with the agreement and Kappa of the intra-observer variability.

The intra-observer reliability was, according to the table of Landis and Koch (table III), substantial for 8 items (pain, 2 items of symmetry, voluntary contraction, endurance, voluntary relaxation, involuntary contraction and perineal movement during coughing). The inter-observer reliability of pain assessments was almost perfect. Substantial inter-observer reliability was found for visual inspection of relaxation after contraction and the presence of incontinence during coughing and for digital assessment of voluntary contractions. Overall, there was very little variability in the PFMF scores between the women.

Table IV Overall findings of agreement of PFM (dys)function (Agr.%/K) and K_w.

	Intra-observer reliability			Inter-observer reliability		
	K agr %	Kw	95 % CI	K agr %	Kw	95 %CI
Visual inspection						
inward movement	100	*)	0	100	*)	*)
co-contraction visible	**75**	**.48**	0.20 – 0.69	**61**	**.52**	0.34 – 0.69
Relaxation	97.6	*)	0	**97.6**	**.75**	0.62 – 0.85
perineal movement during coughing	**70.7**	**.54**	0.28 – 0.73	44	.33	0.14 – 0.53
Incontinence	97.6	*)	0	**97.6**	**.75**	0.62 – 0.85
perineal movement during straining	90.2	.33	0.03 – 0.58	82.9	.013	0.14 – 0.22
Palpation						
Pain	**89.7**	**.79**	0.60 – 0.87	**89.5**	**.85**	0.76 – 0.91
urethral lift	95.1	*)	0	82.9	.08	–0.09 – 0.30
levator closure	92.7	.39	0.10 – 0.62	**82.9**	**.45**	0.26 – 0.63
symmetry left right	**87.8**	**.64**	0.42 – 0.79	62.5	.16	–0.03– 0.37
symmetry anterior posterior	**89.2**	**.68**	0.46 – 0.82	46.2	.10	–0.08 – 0.32
voluntary contraction	**75.6**	**.67**	0.46 – 0.81	**56.1**	**.64**	0.48 – 0.77
Endurance	**78**	**.76**	0.60 – 0.86	36.6	.37	0.17 – 0.56
fast contraction	**61**	**.60**	0.37 – 0.77	**39**	**.47**	0.29 – 0.65
voluntary relaxation	**87.8**	**.76**	0.59 – 0.87	39	.17	–0.01 – 0.38
Palpation during coughing						
involuntary contraction	**82.9**	**.66**	0.44 – 0.80	46.3	.33	0.14 – 0.53
movement perineum	**95.1**	**.77**	0.61 – 0.87	75.6	.03	–0.13– 0.24
Palpation during straining						
involuntary relaxation	**80**	**.60**	0.36 – 0.79	61	.15	–0.03 – 0.36

*) *the K_w measure could not be calculated because to few differences were observed and scoring results were dichotomized. Values in bold (P <.05)*

Discussion

This is the first study in which a PFMF assessment scheme has been designed on the basis of the new standardised terminology of the ICS. Definitions of dysfunction were transformed into refined outcome measures and the scheme was tested for reliability. Existing assessment schemes are all based on self-formulated definitions.

The PFCAG of the ICS, who is responsible for the new terminology on PFMF, stated that the new definitions are descriptive and meant for daily clinical practice. However, this terminology is vague and not yet well defined. Therefore, to implement this new terminology in an assessment scheme, we performed 6 Delphi rounds to refine the outcome measures and to establish face validity. Several items from existing protocols have been included in the new scheme (Table I). Some items are comparable with those in other schemes and others now have a different outcome measure.

Face validity

Face validity was tested by fully trained pelvic physiotherapists alone (monodisciplinary). Although their level of experience varied, higher face validity could have been reached for example by including gynaecologists in the team of (multi-disciplinary) experts. Furthermore, only a few studies were suitable to support the expert opinions in the preparation of proper definitions. Development of the assessment was therefore troublesome, time-consuming and placed high demands on the participants in the Delphi rounds. The final result is the first complete assessment protocol in accordance with the ICS.

Intra-observer reliability

Intra-observer reliability was moderate to substantial, which is comparable with the other studies by Bo(23), Brink, Devreese and Laycock.

All the *visual inspection* items showed close agreement. This may have been due to the dichotomization of items and the low level of variability in PFMF scores between the women. For example, most of the women had a positive score on the item 'seeing an inward movement'. Observation of an inward movement has been studied earlier.[10,23] Bo demonstrated an inward movement of 10.8 mm (SD 6.0) during MRI in the sitting position and confirmed this later by ultrasound in the supine position.[24] Apparently, even in the new scheme, the definition does not yet make sufficient distinction. Two items had only moderate intra-observer reliability: visual inspection of co-contractions and perineal movement during coughing (.48 and .54). Probably,

fatigue played a role in the 4th examination. Although we performed the four assessments over the period of one hour to enable the women to rest as much as possible, we cannot be sure that fatigue did not occur. Until now, it is unclear how four consecutive tests within one hour affect PFMF. In the scheme developed by Devreese et al. (2004) 'perineal movement during coughing' scored the abdominal wall activity and perineal activity, which resulted in 1 cm of movement. However, this item does not form part of the ICS terminology. Therefore we excluded abdominal wall activity from our test on perineal movement during coughing.

Relaxation (after a voluntary contraction), inward movement and perineal movement during straining showed high agreement, weighted Kappas could only be calculated on the straining part of the scheme. It was found that relaxation had high intra-observer reliability agreement and formed a good measure. As the variability within the group was low, it was impossible to calculate weighted Kappas of the intra-observer reliability scores.

PFM strength during voluntary contraction was tested using *palpation* (in line with the regular method), and classified as absent, weak, normal and strong, just like in the Brink score. Palpation showed substantial reliability with a K_w of .67 for intra-observer reliability. This is in agreement with the study by Bo and Finckenhagen [25], although they stated that categorizing the results on 3- or 5-point scales may not have sufficient sensitivity to differentiate between individuals. This was also confirmed in the studies by Frawley et al.[26] and Fitzgerald et al.[19] However, we followed new definitions proposed by the ICS and would like to emphasize that strength measurement is only one aspect of PFMF and as such, only forms a small part of the whole assessment scheme.

Endurance showed substantial (.76) intra-observer reliability. This was in conformity with the study by Bo and Finckenhagen [23] but disagreed slightly with the study by Devreese.[4] It is possible that this difference was caused by the study population of Devreese, which comprised continent and incontinent women, that is, optimal and minimal PFMF. In our group PFMF did not show any great variability. To test endurance we scored the quality of a voluntary contraction during ten seconds in the same way as Devreese et al.[4] and Laycock in the PERFECT scheme. In contrast, the Brink score only uses a maximum of three seconds. It is our opinion that ten seconds are necessary to test endurance properly.

Fast contractions were also tested in conformity with existing methods and showed moderate agreement (.60). This outcome is difficult to compare to other studies, because different methods were used. In the study by Devreese [4], only the contraction speed was measured, and not the number of fast contractions. We proposed to assessing fast contractions in the new scheme,

based on our hypothesis that in daily life, frequent fast contractions are necessary to coordinate well-timed reflex contractions. Thus, the number of contractions is also important.

Pain showed substantial intra-observer reliability (.79). This item was not scored in earlier PFM assessments. Pain can influence PFMF [27] and the high K_w in our study proved the high reliability. We regard information about pain to be essential in the assessment of PFMF.

Palpation of asymmetry showed substantial (.64 -.68) intra-observer reliability. This test is important, because Dietz [28] has recently found that it can help to diagnose trauma in the levator ani. They suggested to add strength asymmetry measurements to PFMF assessment schemes. In our assessment scheme, asymmetry was tested in a voluntary contraction, without asking for maximal strength. Based on the findings of Dietz et al.[28] we recommend the addition of asymmetry assessments, especially strength measurements, to gain insight into the possible presence of levator trauma.

Closing of the levator was also included, but intra-observer reliability was low (.39), whereas overall agreement was 92.7%. This was probably due to fatigue during the later measurements. Fatigue is known to influence total PFMF and as stated above, strength is not the only function that is responsible for good and adequate PFMF.[4,29,30]

Urethral lift during a contraction showed high agreement, but no K_w. Our decision to score any sign of upward lift as positive was probably the cause of this result. Urethral lift is tested in 4 items in the Brink-score and demonstrated a moderate reliability (.51).[11] This point could be taken into account when the PFCAG make adjustments to PFMF terminology in the future.

Relaxation after a contraction showed high intra-observer reliability (.76). However, the scoring of relaxation according the ICS is disputable, because they only define three steps: complete (relaxation beyond the resting level), partial (relaxation until the resting level) and absent (no relaxation palpable). We feel that incomplete relaxation is missing from the terminology (i.e. relaxation that does not (quite) reach the resting level. This point caused a great deal of discussion between our examiners. In clinical practice, we are used to scoring relaxation on the 3 ICS items and on our own 'incomplete relaxation' item, which might be the reason for the low intra-observer reliability scores.

During coughing, we tested involuntary, reflex contractions of the pelvic floor muscles by looking for inward movements and urethral lift. Furthermore, we tested involuntary relaxation during straining by looking for downward movements of the perineum. It is important to test the item of involuntary contraction defined in the ICS terminology, because downward movement of the perineum and incontinence during a sudden increase in IAP (not to be

confused with straining for defaecation) are the result of inadequate contraction of the pelvic floor muscles.[14,15,31,32] The scoring of involuntary movements during coughing and straining showed substantial intra-observer reliability. Our reflex contraction results seem to be in line with Devreese [4] whose the intra-observer reliability was almost perfect (.88). However, we wish to emphasize that in general good voluntary contraction seen in the assessment that results in positive urethral lift, is no guarantee that effective reflex contractions always occur when needed.[4,14] The outcomes of these items can form helpful indicators in the development of a functional training program.

Inter-observer reliability

Inter-observer reliability was generally disappointing. Although we endeavoured to avoid any bias in the assessments, we were unable to achieve reliability on many of the items. Fatigue may form an important explanation for the changes in PFMF during the test scheme and the low agreement scores. Other explanations might be a learning effect by the women and inter-tester differences. Although the verbal instructions were standardized, the tone and personality of the examiner can interfere also.

Substantial agreement (.75) was seen in the visual inspection part of the scheme that tested relaxation after a contraction and the symptom of urinary incontinence. Apparently, the contrasts in function are clearly visible. A few items on the scheme were good: pain (.85) and a voluntary contraction (.64), while two items were moderate: fast contractions (.47) and the levator closure (.45).

As pain has never been scored in the earlier studies on PFM assessments, our results cannot be compared to the literature. This also applies to levator closure that has not been tested before. We believe that this item also needs further refinement to increase inter-tester reliability. Due to different testing methods and different outcome measures, not all of our reliability scores of voluntary contractions and fast contractions are comparable with other studies.

Discrepancies between intra-observer reliability and inter-observer reliability

There were large differences in intra-observer and inter-observer reliability on the outcome symmetry, with high scores on intra-observer reliability (K_w .64 and .68) and low scores on inter-observer reliability (K_w .16 and .10). An explanation probably lies in different interpretations by the three

examiners. Therefore, this item also needs more refinement and/or a different approach.

Palpation of the involuntary contraction of the pelvic floor muscles and movement of the perineum showed substantial intra-observer reliability (.66), but only moderate inter-observer reliability (.33). Therefore, these items need further refinement.

This study is an important step forward in the definition of outcome measures to assess PFMF, but it has its limitations. Our study group appeared to be less heterogeneous than we would have liked. Age did not have a normal distribution, but as none of our statistical analyses required the assumption of normality of age, this characteristic was irrelevant. The definitions of the ICS need further refinement before they can be incorporated into an assessment scheme that is also suitable for research purposes.

Conclusion

Our new PFMF assessment scheme was designed according to the standardized terminology of the ICS. Based on the moderate to substantial intra-observer reliability and face validity, it can be considered reliable in clinical practice. Before implementation for research purposes, the outcome measures need detailed refinement in view of the disappointing inter-observer reliability.

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References

1. Eliasson, B, Shukla, PK. Dynamics of whistler spherom aks in magnetized plasmas. Phys Rev Lett 2007;99:205005.
2. Lagro-Janssen, TL, Debruyne, FM, Smits, AJ, Van Weel, C. Controlled trial of pelvic floor exercises in the treatment of urinary stress incontinence in general practice. Br J Gen Pract 1991;41:445-9.
3. Bo, K, Talseth, T, Holme, I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women Bmj 1999;318:487-93.
4. Devreese, A, Staes, F, De Weerdt, W, Feys, H, Van Assche, A, Penninckx, F, et al. Clinical evaluation of pelvic floor muscle function in continent and incontinent women Neurourol Urodyn 2004;23:190-7.
5. Bo, K, Sherburn, M. Evaluation of female pelvic-floor muscle function and strength. Phys Ther 2005;85:269-82.
6. Dietz, HP. Why pelvic floor surgeons should utilize ultrasound imaging. Ultrasound Obstet Gynecol 2006;28:629-34.
7. Thompson, JA, O'sullivan, PB. Levator plate movement during voluntary pelvic floor muscle contraction in subjects with incontinence and prolapse: a cross-sectional study and review. Int Urogynecol J Pelvic Floor Dysfunct 2003;14:84-8.
8. Brink, CA, Sampselle, CM, Wells, TJ, Diokno, AC, Gillis, GL. A digital test for pelvic muscle strength in older women with urinary incontinence. Nurs Res 1989;38:196-9.
9. Laycock, J. Incontinence. Pelvic floor re-education. Nursing (Lond) 1991;4:15-7.
10. Bo, K. Pelvic floor muscle strength and response to pelvic floor muscle training for stress urinary incontinence Neurourol Urodyn 2003;22:654-8.
11. Brink, CA, Wells, TJ, Sampselle, CM, Taillie, ER, Mayer, R. A digital test for pelvic muscle strength in women with urinary incontinence. Nurs Res 1994;43:352-6.
12. Hundley, AF, Wu, JM, Visco, AG. A comparison of perineometer to brink score for assessment of pelvic floor muscle strength. Am J Obstet Gynecol 2005;192:1583-91.
13. Messelink, B, Benson, T, Berghmans, B, Bo, K, Corcos, J, Fowler, C, et al. Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn 2005;24:374-80.
14. Miller, JM, Perucchini, D, Carchidi, LT, Delancey, JO, Ashton-Miller, J. Pelvic floor muscle contraction during a cough and decreased vesical neck mobility Obstet Gynecol 2001;97:255-60.
15. Constantinou, CE, Hvistendahl, G, Ryhammer, A, Nagel, LL, Djurhuus, JC. Determining the displacement of the pelvic floor and pelvic organs during voluntary contractions using magnetic resonance imaging in younger and older women. BJU Int 2002;90:408-14.

16. Amarenco, G, Ismael, SS, Lagauche, D, Raibaut, P, Rene-Corail, P, Wolff, N, et al. Cough anal reflex: strict relationship between intravesical pressure and pelvic floor muscle electromyographic activity during cough. Urodynamic and electrophysiological study J Urol 2005;173:149-52.
17. Deffieux, X, Hubeaux, K, Porcher, R, Ismael, SS, Raibaut, P, Amarenco, G. Pelvic floor muscle activity during coughing: altered pattern in women with stress urinary incontinence. Urology 2007;70:443-7; discussion 447-8.
18. Deffieux, X, Hubeaux, K, Porcher, R, Ismael, SS, Raibaut, P, Amarenco, G. Abnormal pelvic response to cough in women with stress urinary incontinence. Neurourol Urodyn 2007.
19. Fitzgerald, MP, Burgio, KL, Borello-France, DF, Menefee, SA, Schaffer, J, Kraus, S, et al. Pelvic-floor strength in women with incontinence as assessed by the brink scale. Phys Ther 2007;87:1316-24.
20. Black, N, Murphy, M, Lamping, D, Mckee, M, Sanderson, C, Askham, J, et al. Consensus development methods: a review of best practice in creating clinical guidelines. J Health Serv Res Policy 1999;4:236-48.
21. Koch, GG, Landis, JR, Freeman, Jl, Freeman, Dh, Jr., Lehnen, RC. A general methodology for the analysis of experiments with repeated measurement of categorical data. Biometrics 1977;33:133-58.
22. Feinstein, AR, Cicchetti, Dv. High agreement but low kappa: I. The problems of two paradoxes. J Clin Epidemiol 1990;43:543-9.
23. Bo, K, Finckenhagen, Hb. Vaginal palpation of pelvic floor muscle strength: inter-test reproducibility and comparison between palpation and vaginal squeeze pressure Acta Obstet Gynecol Scand 2001;80:883-7.
24. Bo, K, Lilleas, F, Talseth, T, Hedland, H. Dynamic MRI of the pelvic floor muscles in an upright sitting position Neurourol Urodyn 2001;20:167-74.
25. Bo, K, Finckenhagen, HB. Is there any difference in measurement of pelvic floor muscle strength in supine and standing position? Acta Obstet Gynecol Scand 2003;82:1120-4.
26. Frawley, HC, Galea, MP, Phillips, BA, Sherburn, M, Bo, K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. Neurourol Urodyn 2006;25:236-42.
27. Van Der Velde, J, Laan, E, Everaerd, W. Vaginismus, a component of a general defensive reaction. an investigation of pelvic floor muscle activity during exposure to emotion-inducing film excerpts in women with and without vaginismus. Int Urogynecol J Pelvic Floor Dysfunct 2001;12:328-31.
28. Dietz, HP, Shek, C. Levator avulsion and grading of pelvic floor muscle strength. Int Urogynecol J Pelvic Floor Dysfunct 2007.
29. Theofrastous, JP, Wyman, JF, Bump, RC, Mcclish, DK, Elser, DM, Bland, DR, et al. Effects of pelvic floor muscle training on strength and predictors of response in the treatment of urinary incontinence. Neurourol Urodyn 2002;21:486-90.

30. Deffieux, X, Hubeaux, K, Damphousse, M, Raibaut, P, Sheikh Ismael, S, Thoumie, P, et al. Perineal neuromuscular fatigue. Ann Readapt Med Phys 2006;49:331-6, 413-7.
31. Theofrastous, JP, Wyman, JF, Bump, RC, Mcclish, DK, Elser, DM, Robinson, D, et al. Relationship between urethral and vaginal pressures during pelvic muscle contraction. The Continence Program for Women Research Group. Neurourol Urodyn 1997;16:553-8.
32. Peng, Q, Jones, R, Shishido, K, Constantinou, CE. Ultrasound evaluation of dynamic responses of female pelvic floor muscles. Ultrasound Med Biol 2007;33:342-52.
33 Fleiss JL and Cohen J. The equivalence of weighted kappa and the ICC as measures of reliability. Educational and Psychological Measurement 1973; 33, 613-619.

Chapter 10

Pelvic floor muscle function in a general female population in relation with age and parity and the relation between voluntary and involuntary contractions of the pelvic floor musculature

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Abstract

Objective To describe pelvic floor muscle function (PFMF) in relation to age and parity in a general female population and to test whether strength/endurance measurements represent all functions of the pelvic floor musculature.
Methods Cross-sectional study on 95% of the women aged 45-85 years from a small Dutch town. Validated questionnaires were used to obtain general information and vaginal examination to test PFMF was performed on 649 women. Chi-square tests were used to analyse the relation between PFMF versus age and parity. ANOVA was used to compare muscle strength and endurance to the other PFMF items.
Results Response rate to the questionnaire was 62.7% (1,869/2,979). PFM strength and endurance are not positively associated with the effective involuntary muscle contractions (IMC) during coughing.
Conclusion Voluntary muscle contractions decreased with age, but there was no relation with parity. Muscle strength and endurance measurements alone are not sensitive enough to determine PFMF.

PréCIS

Strength and endurance of the pelvic floor musculature are not significantly related to effective involuntary contraction to counteract sudden increases in intra-abdominal pressure.

Introduction

The pelvic floor musculature (PFM) is a muscular layer that supports the pelvic organs. PFM function (PFMF) depends on the anatomical position of the muscles, the resting tone and the integrity of the fascia. When there is an increase in intra- abdominal pressure (IAP) e.g. during coughing, the PFM must contract (involuntarily) to maintain the support of the pelvic organs. Voluntary contraction of the PFM results in the inward movement of the perineum and upward movement of the pelvic organs. The urethra, anus and vagina also close.[1] Normal PFMF plays an important role in maintaining urinary or faecal continence and can function as a defence mechanism against sexual intercourse.[2]

After voluntary and involuntary contractions of the PFM, relaxation must result in the termination of urethral, vaginal and anal closure. Although it is complicated to test basic PFM tone, studies have been performed using e.g. a dynamometer [3], but this technique is still at the laboratory model stage. PFM tone scores obtained during manual testing were unreliable. It is difficult to evaluate and compare PFMF, because there are many different methods and scales. Over the past 20 years, three pelvic floor muscle assessments have been used most commonly: the Laycock PERFECT scale with a 6-point scale to score muscle strength and endurance, the number of repetitions and fast contractions; the Brink score to assess muscle strength, urethral lift and muscle endurance, all with 4-point scales; the Devreese assessment scale, with more PFMF items, including co-contraction of the Transverse Abdominal Muscles (TrAM).[4-6] However, many items are still missing form all these assessment methods.

The Pelvic Floor Clinical Assessment Group of the International Continence Society (ICS) 2005 has standardised the terminology relevant to pelvic floor muscle functioning.[7] In 2008, this terminology was tested for face validity and reliability.[8]

Recently, Talasz et al.[9], used the ICS terminology to study PFMF [7] in geriatric women with urinary incontinence. They demonstrated that more than 87% of the patients were not aware of the location of the pelvic floor and were unable to perform any voluntary or involuntary contractions of the PFM. It was presumed that these women had never learned to use their PFM in early life and that this had led to PFM dysfunction and urinary incontinence as they became older. In a second study, Talasz tested PFMF in a random group of Austrian women who were visiting a gynaecological outpatient clinic because of non-pelvic floor disorders.[10] Unfortunately, PFM strength was tested with the Oxford grading system that differs from the ICS terminol-

ogy, in which muscle strength is defined as absent, weak, normal or strong. Furthermore, inter-tester reliability did not form part of their assessment.

The first treatment option for many pelvic floor disorders is PFM training. However, pelvic floor physiotherapists lack relevant information about PFMF in relation to age and parity in a general population. In current clinical practice, the PFM are generally only tested for strength and endurance, but it is not yet clear whether these two functions cover total PFMF as proposed by the ICS terminology. Therefore, we performed a cross-sectional study to obtain normative data on PFMF in relation to age and parity from a general female population aged 45-85 years. In addition, we analysed whether muscle strength and endurance affected voluntary and involuntary PFM contractions.

Material and methods

A cross-sectional study was performed on a general population of mostly white women aged 45 to 85 years, living in the Netherlands. A more detailed description of the study is already been published.[11] The total population of women aged 45-85 years (n=2,979 out of 16,000 citizens) registered on the patients lists of eight out of the nine general practices in the town of Brielle (near Rotterdam, the Netherlands) were approached to participate in the present study. All the women were asked to complete a self-report questionnaire. Non-responders received a reminder eight weeks later after the first contact that contained the same questionnaire. Data were collected anonymously.

Vaginal examination

From the total population, 800 women were randomly selected for PFMF assessment. All of them gave informed consent. Table I presents the PFM assessment scale, the criteria and verbal instructions, in conformity with ICS terminology.[7] Data were obtained by means of visual inspection and palpation of voluntary muscle contraction (VMC) and effective involuntary muscle contraction (IMC) during coughing (that should prevent the perineum from moving in the caudal direction) and muscle relaxation during straining. One gynaecologist and one physiotherapist performed the vaginal examinations. Attention was paid to extensive training of the two examiners before starting the study to 100% agreement, because the two examiners tested half of the women each.

Statistical analysis

Chi-square tests and tests for trend were used to compare individual PFM items (with yes/no answers or 3-category scores) between four ten-year age categories and four parity categories (0, 1, 2 and ≥ 3). Analysis of Variance (ANOVA) was used to compare the PFM items voluntary muscle contraction and endurance (scored on a quantitative scale) to the characteristics. Analyses were performed using the Statistical Package for Social Science (SPSS Inc) 15.0. The Medical Ethics Research Committee (METC) of the Erasmus MC Rotterdam approved this study.

Results

Response rate

The response rate to the questionnaire was 62.7% (1,869/2,979). In the group of 1,869 responders, 472 (25.2%) women refused to participate, 1,397 (74.8%) women (group 1 in figure I) agreed to fill out the large questionnaire and 1140 (60.9%) agreed to fill out the questionnaire and undergo vaginal examination. In group 2, 800 out of the 1,140 women were selected at random and sent an invitation to undergo vaginal examination: 649 women complied (81.1%). Thus, 46% of the total study group underwent vaginal examination (649/1,397). In the non-responder group (group 3), 59% completed and returned the short questionnaire (620/1,051).

Table I PFM assessment (with verbal instructions between parenthesis)

	outcome	outcome measures
Visual inspection		
co-contraction visible	yes	any co-activity of muscles other than TrAb
	no	no co-activity of other muscles visible
Palpation during voluntary muscle contraction		**abbreviation: VMC**
('lift and squeeze your PFM' and if this was not helpful enough, 'try to avoid loss of urine or flatus)'		
urethral lift	yes	any urethral lift palpable
	no	no urethral lift palpable
inward movement perineum	yes	any inward movement of the perineum
	no	no inward movement of the perineum
	down-ward	any downward movement of the perineum
levator closure	yes	any levator closure movement palpable
	no	no levator closure movement palpable
voluntary relaxation	complete	direct beyond rest level
	partly	direct relaxation to rest level
	absent	no relaxation palpable
maximum voluntary contraction *('lift and squeeze your PFM as hard as possible')*	strong	strong closure and lifting, cranio-anterior movement palpable
	normal	closure and lifting, cranio-anterior movement palpable
	weak	short contraction, no closure palpable
	absent	no contraction
endurance	1 till 10	
('make a steady but firm contraction and hold it as long as you can, while repeating hold and hold and hold')		
Palpation during involuntary muscle contraction		**abbreviation: IMC**
during coughing *('cough forcefully')*		
movement perineum	yes	no or ineffective contraction that allows any downward movement of the perineum
	no	effective IMC (no downward movement of the perineum)
Palpation during involuntary muscle relaxation		**abbreviation: IMR**
during straining *(' give a strong push')*		
involuntary relaxation	yes	any caudal movement of the perineum
	no	no downward movement

Baseline characteristics

For detailed description of the baseline characteristics of the total study population we refer to a previous publication.[11] No significant differences were found between responders and non-responders. Table II presents the overall results of PFMF obtained from this general population. Although visual inspection showed that only 8.6% were incontinent during coughing, palpation indicated that 48.5% were able to perform effective IMC during coughing. In table II, PFMF results are also presented in relation to age, analysed with the Chi-square test and test for trend. Decreases in most of the PFM functions were found with increasing age, e.g. visible co-contractions, urethral lift, levator closure, inward movement of the perineum, muscle endurance, IMC and involuntary muscle relaxation. Table III presents PFMF in relation to parity. No significant differences were observed between the nulliparous women and the parous women. A trend was seen in levator closure ($p < .001$).

Muscle strength and endurance versus PFMF

Table IV shows the results of the Analysis of Variance (ANOVA) on PFM strength and endurance in relation to the other PFMF items. All the items demonstrated significant associations, except for effective IMC during coughing: fewer women with normal or strong PFM were able to perform adequate IMC to resist a sudden increase in IAP during coughing (41.6% and 40.6%) than the women with absent or weak PFM (52.9% and 61.5%). Women with strong PFM showed less co-contraction, better urethral lift and levator closure, better relaxation and involuntary muscle relaxation during straining (that resulted in downward movement of the perineum).

Table II Pelvic Floor muscle function (PFM) in women versus age in 10 year age groups (individual PFM items with yes/no scores or three category scores

		Overall n=649	45-55 n=292	56-65 n=217	66-75 n=100	76-85 n=39	p value
Visual inspection							
co-contraction visible	yes	34.6	28	34.6	39	71.8	<.001
	no	65.4	72	65.4	61	28.2	
Palpation during voluntary muscle contraction							
urethral lift	yes	62.4	70.8	58.1	61.2	28.2	<.001
	no	37.6	29.2	41.9	38.8	71.8	
inward movement perineum	yes	77.0	82.2	75.3	74.7	48.7	<.001
	no	22.5	17.4	23.3	25.3	48.7	
	downward	.8	.3	1.4	0	2.6	
levator closure	yes	61.9	69.6	58.8	61.6	21.6	<.001
	no	38.1	30.4	41.2	38.4	78.4	
voluntary relaxation	good	51.3	56.1	45.8	51.1	47.4	.111
	delayed	28.5	26.6	31.5	27.2	28.9	
	incomplete	20.2	17.3	22.7	21.7	23.7	
voluntary contraction	absent	5.2	5.1	5.5	5	5.1	<.001
	weak	31.6	21.2	37.3	41	53.8	
	normal	58.2	66.4	53.9	50	41	
	strong	4.9	7.2	3.2	4	0	
endurance mean in sec.	0-10 sec	6.24	6.83	5.93	5.84	4.56	<.001
Palpation during involuntary muscle contraction during coughing							
downward movement perineum	yes (ineff. IMC)	51.5	61	46.3	34	53.8	<.001
no downward movement perineum	no (eff. IMC)	48.5	39	53.7	66	46.2	
Palpation during involuntary muscle relaxation during straining							
caudal perineal movement	yes	89.9	93	90.3	84.7	76.9	<.001
no caudal perineal movement	no	10.2	7	9.7	15.3	23.	

Table III Pelvic floor muscle function (PFMF) versus parity (individual PFM items with yes/no scores or three category scores)

		0 n=49	1 n=86	2 n=321	≥ 3 n=183	Total (n=)	p value
Visual inspection							
co-contraction visible	yes	33.1	33.7	35.8	33.3	34.6 (220)	.973
	no	66.7	66.3	64.2	66.7	65.4 (415)	
Palpation during voluntary muscle contraction							
urethral lift	yes	73.5	63.9	61.2	62.1	62.8 (388)	.227
	no	26.5	36.1	38.8	37.9	37.2 (230)	
inward movement perineum	yes	79.6	77.1	76.4	77.2	77 (482)	.936
	no	18.4	21.7	22.6	22.8	22.2 (139)	
	downward	2	1.2	1	0	.8 (5)	
levator closure	yes	73.5	63.9	61.2	62.1	62.1 (384)	.062
	no	13	34.9	38.6	41.1	37.9 (234)	
voluntary relaxation	good	51.1	56.1	49.5	53.6	51.7 (307)	.783
	delayed	29.8	23.2	29	29.2	28.3 (168)	
	incomplete	19.1	20.7	21.5	17.3	20 (119)	
voluntary contraction	absent	2	8.1	5.3	4.9	5.3 (34)	.427
	weak	20.4	30.2	32.2	32.8	31.2 (199)	
	normal	73.5	59.3	56.6	57.4	58.5 (373)	
	strong	4.1	2.3	5.9	4.9	5 (32)	
endurance	0-10 sec	6.26	7.31	6.07	6.10	6.37 (3.23)	.103
Palpation during involuntary muscle contraction during coughing							
downward movement perineum	yes (ineff. IMC)	51	50	52.6	51.9	52 (332)	.815
no downward movement perineum	no (eff. IMC)	49	50	47.4	48.1	48 (307)	
Palpation during involuntary muscle relaxation during straining							
caudal perineal movement during straining	yes	89.6	89.4	90.2	91.1	90.3 (568)	.647
no caudal movement	no	10.4	10.6	9.8	8.9	9.7 (61)	

Table IV PF muscle strength and endurance versus all the other PFMF items

PFM Function		PFM strength (Chi-square)					endurance (ANOVA)		
		Absent n=34	Weak n=205	Normal n=377	Strong n=33	p value	mean	SD	p value
Visual inspection									
co-contraction visible	yes	60.6	46.3	28.1	9.4	<.001	4.74	3.33	<.001
	no	39.4	53.7	71.9	90.6		7.04	2.96	
Palpation during voluntary muscle contraction									
urethral lift	yes	2.9	23.8	85.1	96.6	<.001	7.90	2.31	<.001
	no	97.1	76.2	14.9	3.1		3.47	2.78	
inward movement perineum	yes	5.9	49.5	96.5	93.5	<.001	7.37	2.58	<.001
	no	91.2	48.5	3.5	6.5		2.63	2.65	
	downward	2.9	2.0	0	0		1.80	1.10	
levator closure	yes	0	31.6	80.4	96.6	<.001	7.83	2.35	<.001
	no	100	68.4	19.6	3.1		3.69	2.94	
voluntary relaxation	good	10.3	30.1	62.4	87.5	<.001	7.42	2.94	<.001
	delayed	3.4	37.1	27.8	9.4		6.16	2.67	
	incomplete	86.2	323.8	9.8	3.1		6.31	3.28	
voluntary contraction	absent						.24	1.05	
	weak						3.88	2.58	
	normal						7.87	2.21	
	strong						8.72	2.28	<.001
endurance mean (SD)	0-10 sec	.23	3.88	7.87	8.72	<.001			
Palpation during involuntary muscle contraction during coughing									
downward movement perineum	yes (ineff. IMC)	47.1	38.5	58.4	59.4	<.001	6.57	3.42	<.01
no downward movement perineum	no (eff. IMC)	52.9	61.5	41.6	40.6	<.001			
Palpation during involuntary muscle relaxation during straining									
caudal perineal movement	yes	67.6	84.0	94.9	90.6	<.001			
no caudal movement perineum	no	32.4	16.0	5.1	9.4		6.51	3.17	.001

Discussion

This study investigated pelvic floor muscle function (PFMF) in relation to age and parity in a general female population and tested whether strength/endurance measurements all functions of the pelvic floor musculature.

PFMF overall and in relation to age, table II

Normal or strong PFM during VMC was found in 63% of the women and they were able to achieve urethal lift and levator closure. However, only half of the women (51.3%) were able to relax voluntarily after VMC, which indicates that the other half of the women were unable to relax properly. This is in contrast with the involuntary muscle contraction.

Only half of the women (48.5%) performed an effective PFM contraction during coughing, while almost all women (90%) were able to relax involuntary during straining. The reason is unclear. We hypothesize that postural functions of the PFM can play a role in voluntary contractions and delayed relaxation.[12-13] However, this does not explain why half of the women had ineffective involuntary contractions. The overall results cannot be compared to other studies, because other studies did not use the ICS terminology or did not assess a general population.

Significant relations were found between PFMF and age. All items had decreasing scores with increasing age. Only voluntary relaxation was not significant. These findings can be attributed to the normal process of aging: muscle mass starts to decrease in the 5th decade and decreases drastically after the age of 60 years.[14] Our results were also in line with other studies on pelvic floor musculature.[15-17]

Parity table III

Surprisingly, no significant differences in PFMF were found between the nulliparous women and any of the parous groups. Not even muscle strength was significantly related, while muscle endurance only demonstrated a trend.

Muscle strength and endurance versus other PFMF items table IV

Our second objective was to test whether the assessment of PFM strength and endurance alone represent all functions of the PFMF. Indeed, a stronger PFM was significantly related to a proper PFMF as was a weak or absent PFM related to a non-proper PFMF. However, this was only the case during VMC. A significant observation was done during IMC for in women scoring absent (52.9%) or weak (61.5%) PFM strength an effective PFMF was present: in these women no downward movement of the perineum occurred during coughing. This was the opposite in women with stronger PFM. This demonstrates that

PFM strength and endurance do not represent all functions of the PFM. We hypothesize that the mechanisms of volunatray and involuntary control (reflexes) are responsible.[18-20] It might be possible that during reflexes, motor units of the PFM will be activated which are not active during voluntary contraction. Our finding was in contrast with the results reported by Talasz, who demonstrated a relation between muscle strength and involuntary muscle contraction. However, this can be explained by the different scoring methods: in the study by Talasz, the presence of pre-contraction was scored, but not whether this IMC was effective and prevented the perineum from moving in the caudal direction during an increase in IAP when coughing. In addition, the mean age in the study by Talasz was much younger (41.2 yrs/18-79 yrs versus 56 yrs/45-85 yrs) and it was not performed on a general population.[10]

According to our clinical experience the past ten years, only VMCs have been used to test awareness of the PFM, muscle strength, muscle endurance, timing and urethral lift.[4-5] In our opinion, several items are missing, especially levator closure, IMC during coughing and involuntary relaxation during straining.

It is of even more concern that a study by Davis and Kumar demonstrated that PFMF assessment is often neglected during gynaecological consultations visit.[21]

Strengths and limitations of the study

One of the strengths of our study was the ethnic homogeneity, because almost all of the women were white, which eliminated racial bias from the results. Furthermore, broad data were obtained from a large general study group using a questionnaire and vaginal examination.

Although this study was performed on a general female population, the mean BMI of 25 and the 98% white race mean that caution must be taken if the results are extrapolated to other general populations.

A limitation can be a possible bias in the women who volunteered to undergo the vaginal examination. However, from the 1,397 women that filled in the questionnaire, 81.6% (1,140/1,397) were willing to participate in the examination.

Another limitation can be the reliability of the assessment scale. Since only a reasonable intra-rater reliability was scored we did not enlarge the number of examiners. Nevertheless, by training the examiners to 100% agreement prior to the research we expect to have increased the reliability. Of course the assessment tool needs further study to develop a tool that can be used in science by every researcher. Although face validity of the assessment tool has been tested, no construct validity research has been performed.

The assessment did not include measurements of contractions before coughing because this requires equipment. Therefore, we focused on the effectiveness of the pre-cough contractions by observing the movement of the perineum.

Conclusions

Data on the prevalence of a wide range of PFMF items obtained from this general female population showed that PFMF differed significantly between the age groups and decreased with increasing age. In contrast, no significant differences were observed between the different parity groups. Muscle strength and endurance were related to a proper voluntary PFMF, but not related to the ability to achieve effective IMC. Therefore, the implication for clinicians is that voluntary and involuntary muscle contractions should be included in PFM assessment to establish whether PFMF is involved in the patient's presenting symptoms.

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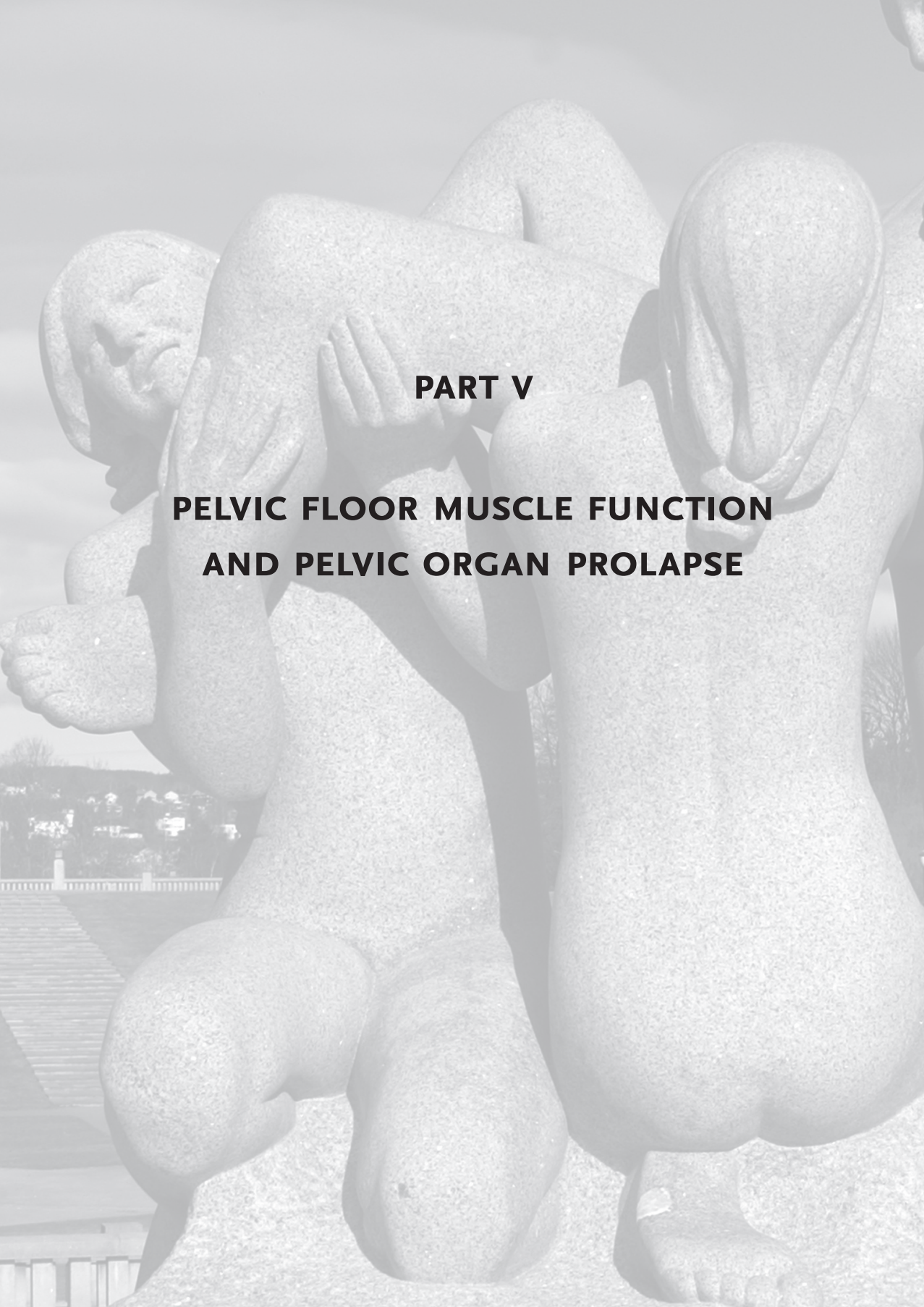
References

1. DeLancey JO (1997) The pathophysiology of stress urinary incontinence in women and its implication for surgical treatment. World J Urol; 15(5):268-74.
2. Van Der Velde J, Laan E, Everaerd W (2001). Vaginismus, a component of a general defensive reaction. An investigation of pelvic floor muscle activity during exposure to emotion-inducing film excerpts in women with and without vaginismus. Int Urogynecol J Pelvic Floor Dysfunct;12:328–31.
3. Dumoulin C, Gravel D, Bourbonnais D, Lemieux MC, Morin M (2004) *Reliability of dynamometric measurements of the pelvic floor musculature*. Neurourol Urodyn; 23(2):134-42.
4. Laycock J (1991) Incontinence. Pelvic floor re-education. Nursing (Lond);4:15-7.
5. Brink Ca, Sampselle Cm, Wells Tj, Diokno Ac, Gillis Gl (1989) A digital test for pelvic muscle strength in older women with urinary incontinence. Nurs Res;38:196-9.
6. Devreese A, Staes F, De Weerdt W, et al (2004) Clinical evaluation of pelvic floor muscle function in continent and incontinent women. Neurourol Urodyn;23:190-7.
7. Messelink B, Benson T, Berghmans, Bo K, Corcos J, Fowler C, Laycock J, Huat-Chye Lim P, van Lunsen R, Lycklama a Nijeholt G, Pemberton J, Wang A, Watier A, Van Kerrebroeck P (2005) Standardisation of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the international continence society. Neurourol Urodyn 24:374–380.

8. Slieker-Ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. 2008a. Face validity and reliability of the first digital assessment scheme of pelvic floor muscle function conform the new standardized terminology of the International Continence Society. Neurourol Urodyn.
9. Talasz H, Gosch M, Enzelsberger H, Rhomberg HP (2005) Geriatrische Patientinnen mit Harninkontinenz-Symptomen und ihre Kontrolle über den Beckenboden. Z Gerontol Geriatr 38:424–430.
10. Talasz H, Himmer-Perschak G, Marth E, Fischer-Colbrie J, Hoefner E, Lechleitner M.(2008) Evaluation of pelvic floor muscle function in a random group of adult women in Austria. Int Urogynecol J Pelvic Floor Dysfunct 19(1):131-135.
11. Slieker-ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME (2008b) Symptomatic pelvic organ prolapse and possible risk factors in a general population. Am J Obstet Gynecol.
12. Hodges PW, Sapsford R, Pengel LH (2007) Postural and respiratory functions of the pelvic floor muscles. Neurourol Urodyn 26(3):362-371.
13. Pool-Goudzwaard A, van Dijke GH, van Gurp M, Mulder P, Snijders C, Stoeckart R (2004) Contribution of pelvic floor muscles to stiffness of the pelvic ring. Clin Biomech (Bristol, Avon) 19(6):564-571.
14. Deschenes MR (2004) Effects of aging on muscle fibre type and size. Sports Med; 34(12):809-24.
15. Chen L, Ashton-Miller JA, Hsu Y, DeLancey JO (2006). Interaction among apical support, levator ani impairment, and anterior vaginal wall prolapse. Obstet Gynecol 108(2):324-332.
16. Trowbridge ER, Wei JT, Fenner DE, Ashton-Miller JA, Delancey JO (2007) Effects of aging on lower urinary tract and pelvic floor function in nulliparous women. *Obstet Gynecol*. Mar;109(3):715-20.
17. Perucchini D, DeLancey JO, Ashton-Miller JA, Galecki A and Schaer GN (2002): Age effects on urethral striated muscle. II. Anatomic location of muscle loss Am J Obstet Gynecol; 186: 356.
18. Deindl FM, Vodusek DB, Hesse U, Schussler B (1993) Activity patterns of pubococcygeal muscles in nulliparous continent women, Br J Urol;72-51.
19. Blok BF, van Maarseveen JT, Holstege G (1998). Electrical stimulation of the sacral dorsal gray commissure evokes relaxation of the external urethral sphincter in the cat. Neurosci Lett;249:68-70.
20. Vereecken RL. Derluyn J, Verduyn H (1975) Electromyography of the perineal striated muscles during cystometry. Urol Int;30:92-98.
21. Davis K, Kumar D (2003) Pelvic floor dysfunction: a conceptual framework for collaborative patient-centred care. J Adv Nurs 43(6):555-568.



PART V

PELVIC FLOOR MUSCLE FUNCTION AND PELVIC ORGAN PROLAPSE

Chapter 11

Pelvic floor muscle function in relation to pelvic organ prolapse

Resubmitted in International Urogynaecology Journal June 5th, 2009

Abstract

Objective To examine the relationship between pelvic floor muscle function (PFMF) and pelvic organ prolapse (POP) in a general female population.
Methods Cross-sectional study on women aged 45-85 years. Validated questionnaires were used to assess pelvic floor (muscle) function. POP and PFMF were evaluated with vaginal examination. For statistical analysis Chi-square test for trend and Analysis of Variance (ANOVA) were used.
Results Response rate to the questionnaire was 62.7% (1,869/2,979). No significant differences were found in muscle strength and endurance during voluntary muscle contraction (VMC) between the POP stages. Women with POP stages 1 and 2 were significantly less able to achieve effective involuntary muscle contraction (IMC) during coughing (38.3% and 37.7%) than women without POP (75.2%).
Conclusion Involuntary contraction of the PFM during coughing (that resulted in stabilization of the perineum) was significantly weaker in the women with POP stage 1-2 than in the women without POP.

PRéCIS

Involuntary contraction of the pelvic floor musculature during coughing was significantly weaker in women with pelvic organ prolapse stage I-II than in those without POP.

Introduction

Pelvic organ prolapse (POP) is a common condition that affects around 75% of women of all ages and parity, but it is not always symptomatic.[1] By the age of 79 years, women have an 11% chance of undergoing at least one surgical treatment for incontinence or POP, with a 29.2% risk of recurrent surgery.[2] The medical cost of POP is high (more than one billion dollars a year in the USA) [3] and is expected to increase due to global aging. We are therefore faced with the challenge of obtaining knowledge about its pathophysiology in order to achieve adequate prevention or treatment.[4]

POP has been attributed to a decrease in pelvic floor muscle support that results in widening of the genital hiatus and stretching of the connective tissue, which enables downward movement of the pelvic organs.[5]

Known risk factors for POP are parity, family history, heavy lifting, increased chronic abdominal pressure caused by heavy physical work or lung disease, smoking, surgery for urinary incontinence (UI) or advanced stage POP, overweight, menopause, race and medication.[1,6] Unfortunately, it is not easy to prevent exposure to most of these risk factors.

Although surgery is the preferred treatment, the recurrence of POP after surgical repair reported in one study was 34.6%.[7] It was associated with reduced strength of the levator ani (35.8% versus 0%, p=.017) and a genital hiatus of 5 cm or larger (44.2% versus 27.8%). Therefore, the question arises as to whether surgery is the optimal and only option to treat POP. As its pathogenesis starts with loss of support of the pelvic floor musculature (PFM), training these muscles might be an effective conservative treatment for POP. Support for muscle training was found in the randomized controlled trial by Hagen et al. [8] in which the women with POP stages 1 and 2 showed a decrease in POP symptoms and objective and subjective improvement. The PFM training protocol not only included strength and endurance, but the women were also taught to voluntary contract the pelvic floor muscles prior to activities such as coughing in order to train the involuntary response contraction of the pelvic floor during an increase of intra-abdominal pressure. However, it is not clear whether this training protocol is the optimal answer to conservative treatment. Knowledge is still lacking on PFM functioning in women with POP. Only one study has been performed on the analysis of PFM activity in women with POP prior to corrective surgery.[9] They found a significant relation between weak PFM and severe POP in a multicentre trial, but did not use the standardized PFM terminology, as put forward by the International Continence Society (ICS).[10] Especially the assessment of the involuntary contractions of the PFM was lacking.

In order to design an optimal training programme for the PFM in women with POP, knowledge is required on the relation between PFM functioning (PFMF) (muscle strength, endurance and coordination) and POP stage in a general female population. Therefore, the aims of our study were to determine:

1) the relation between POP and PFMF in women with and without POP symptoms of vaginal bulging;
2) the relation between POP stage and PFMF using the traditional POPQ measurements and a recently developed ICS PFM assessment tool.[11]

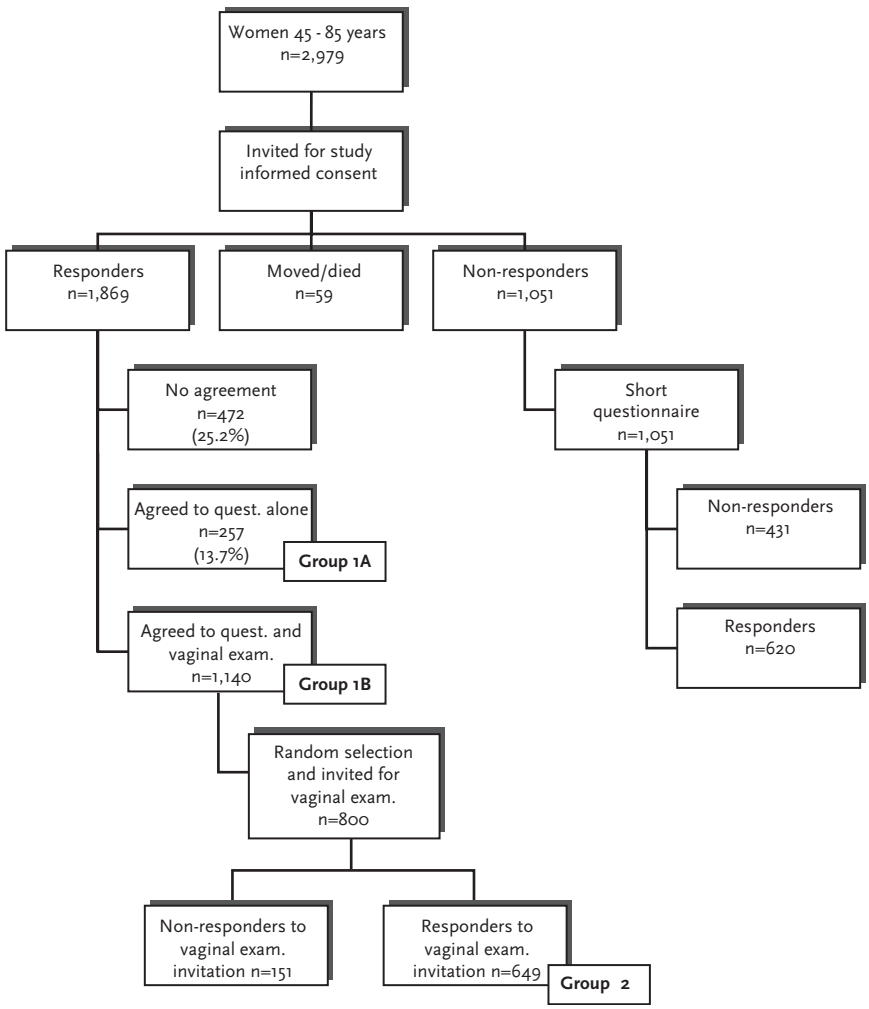
Material and methods

A cross-sectional study was performed on a general population of mostly white women, aged 45 to 85 years, living in a Dutch town. Figure 1 presents the flowchart of the study.

The total population of women aged 45-85 years (n=2,979 out of 16,000 citizens) registered on the lists of eight out of the nine general practices in the town of Brielle (near Rotterdam, the Netherlands) were approached to participate in the present study. As all the inhabitants are obliged to register with a general practitioner, the study population included 95% of the women in this age range in the town. Of the female population 5% was missing since one practice did not participate. The women were sent information about the study and they could enrol by filling out an informed consent form. They were offered three options: to sign a refusal form, to fill out the questionnaire only or to fill out the questionnaire and undergo vaginal examination.

After receiving the informed consent the women who agreed to participate were asked to complete a self-report questionnaire. Non-responders received a reminder eight weeks later that contained the same questionnaire. The data were collected anonymously. To encourage a high response to the questionnaire, we used envelopes with the name and logo of the Erasmus University, coloured paper and stamped-addressed return envelopes.[12] Each reminder included the same questionnaire. To avoid selection bias, non-responders to the reminders were invited to complete a short questionnaire that comprised five questions about: age, parity, presence of stress urinary incontinence (yes/no), faecal incontinence (yes/no) and feeling vaginal bulging (yes/no).

The questionnaires used in this study combined several validated Dutch versions of pelvic floor questionnaires, such as the Urogenital Distress Inventory (UDI) [13] and the Defecation Distress Inventory (DDI).[14] Data extracted from the questionnaires presented in this article, included body mass index (BMI), ethnicity, educational level, parity, menopausal status, hormone replacement therapy (HRT), smoking, previous pelvic floor surgery, family history and heavy physical work undertaken currently or in the past. Women were defined as postmenopausal when their last menstruation had occurred at least 1 year previously.



Vaginal examination

From the group of participants who gave informed consent to undergo vaginal examination (n=1,140, group 1B), eight hundred women were randomly selected for PFMF assessment and POPQ measurement (group 2). (All the response forms were coded with a number that identified the women's age and then a research assistant selected the study sample at random by age). All the vaginal examinations were performed at the women's own general practice. The women were asked to empty their bladder before the examination and were then placed on the examination table in the lithotomy position, with a slightly elevated body and the legs bent to about 30 degrees of flexion.

Table I presents the PFMF assessment method, the criteria and verbal instructions. Voluntary muscle contraction (VMC) and effective involuntary muscle contraction (IMC) during coughing, relaxation and straining were scored by visual inspection and digital palpation. Data were also obtained using reliable POPQ measurement method, developed by the International Continence Society (ICS).[15]

One gynaecologist and one physiotherapist performed all the vaginal examinations. Each participant was assessed once. A great deal of attention was paid to training the two examiners before starting the study. They practiced the vaginal examination protocol until 100% agreement was reached between their scores. This process was performed at the Pelvic Floor Centre of the Erasmus MC, Rotterdam, the Netherlands. The two examiners were blinded to the results of the questionnaire. The Medical Ethics Research Committee (METC) of the Erasmus MC approved this study.

Statistical analysis

Individual PFM items that consisted of yes/no scores or three category scores were compared in relation with the five POPQ stages and the symptom of vaginal bulging in two categories, by means of Chi-square tests and tests for trends. The Chi-square test, which is a test of association between variables, was also used to test for trends in the PFM item voluntary contraction (scored on an ordinal scale). Analysis of Variance (ANOVA), testing for a difference in the mean strength across response categories, was used to compare the same factors in the PFM item muscle endurance (scored as continuous variable). Independent categorical determinants were compared to the dependent outcomes of five stages of POPQ and two degrees of vaginal bulging. Chi-square tests were used to test for trends in the qualitative PFM determinant of voluntary contraction.

Table I PFM assessment with outcome and outcome measures Between parenthesis: verbal instruction. Abbreviations used for voluntary muscle contraction

	outcome	outcome measures
Visual inspection		
co-contraction visible	yes	any co-activity of muscles other than TrAb
	no	no co-activity of other muscles visible
incontinence during coughing	yes	
	no	
Palpation during voluntary muscle contraction		**abbreviation: VMC**
('lift and squeeze your PFM' and if this was not helpful enough, 'try to avoid loss of urine or flatus)'		
urethral lift	yes	any urethral lift palpable
	no	no urethral lift is palpable
inward movement perineum	yes	any inward movement of the perineum
	no	no inward movement of the perineum
	down-ward	any downward movement of the peri-neum
levator closure	yes	any levator closure movement palpable
	no	no levator closure movement palpable
voluntary relaxation	complete	direct beyond rest level
	partly	direct relaxation to rest level
	absent	no relaxation palpable
maximal voluntary contraction *('lift and squeeze your PFM as hard as possible')*	strong	strong closure and lifting cranio-anterior movement palpable
	normal	closure and lifting cranio-anterior move-ment palpable
	weak	short contraction, no closure palpable
	absent	no contraction
endurance	1 to 10	
('make a steady but firm contraction and hold it as long as you can, while repeating hold and hold and hold')		
Palpation during involuntary muscle contraction		**abbreviation: IMC**
during coughing *('cough forcefully')*		
movement perineum	yes	no or ineffective contraction that allows any downward movement of the perineum
	no	effective IMC that results in no downward movement of the perineum
during straining *(' give a strong push')*		
involuntary relaxation	yes	any downward movement of the perineum
	no	no downward movement

(VMC) and involuntary muscle contraction (IMC)

The level of significance was set at $p < .05$. All the analyses were performed using the Statistical Package for Social Science (SPSS Inc) 15.0.

Results

Response rate

The response rate to the questionnaire was 62.7% (1,869/2,979). In the group of 1,869 responders, 472 (25.2%) women refused to participate, 257 (13.7%) women (group 1A in table II) agreed to fill out the large questionnaire only and 1,140 (60.9%) agreed to fill out the questionnaire and undergo vaginal examination (group 1B). Eight hundred out of the 1,140 women were selected at random and sent an invitation to undergo vaginal examination (group 2): 653 women complied (81.6%). Thus, a total of 46.7% women who participated in the study underwent the vaginal examination (653/257+1,140). In the non-responder group who did not respond to the first and second requests to participate in the study (group 3), 59% completed and returned the short questionnaire (620/1,051).

Demographic characteristics

Demographic characteristics of the total study population and the different groups (group 1A, group 1B and the vaginal examination group 2) are presented in table II. No significant differences were found between group 1 (total questionnaire group) and group 3 (the non-responder group who replied to the short questionnaire). In the vaginal examination group, 79 out of the 649 women reported seeing and/or feeling vaginal bulging (scored by the questionnaire). However, no significant differences were found in the demographic characteristics between the three groups.

Table II Baseline characteristics of the total study population and those who underwent vaginal examination expressed as numbers (%) and means

Characteristics of the total study population	Questionnaire Total Groups 1A and 1B n=1,397[*)]	Vaginal exam. Total Group 2 n=649
Mean age (range 45-84 yrs)	**58.0 (SD ± 9.2)**	**58.3 (SD ± 9)**
Mean BMI	n=1,364	n=634
	25.6 (SD ± 3.9)	**25.6 (SD ± 3.7)**
Race	n=1,372	n=640
White	1,351 (96.7)	632 (97.4)
Non-white	20 (1.4)	8 (1.2)
	n=1,340	n=639
Median parity	**2**	**2**
0	120 (8.6)	49 (7.6)
1	215 (15.4)	86 (13.3)
2	675 (48.3)	321 (49.5)
≥3	387 (27.7)	183 (28.2)
Educational level	n=1,374	n=634
Primary only	139 (9.9)	70 (11.1)
Intermediate	1,039 (75.6)	480 (75.7)
Higher	196 (14.3)	84 (13.2)
Menopausal status	n=1,383	n=645
Premenopausal	374 (26.8)	167 (25.7)
Postmenopausal [§)]	1,009 (72.2)	478 (73.7)
Smoking	n=1,382	n=642
Current smoker	280 (20)	134 (20.6)
Surgical history	n=1,384	n=645
Prolapse	103 (7.4)	54 (8.3)
	n=1,382	n=643
Incontinence	47 (3.4)	24 (3.7)
	n=1,383	n=643
Hysterectomy	234 (16.8)	109 (16.8)
Family history	n=985	n=441
Mother POP	359 (25.7)	161 (36.5)
	n=870	n=398
Mother UI	258 (29.7)	122 (30.6)
Heavy physical work [¶)]	n=1,381	n=642
Currently	269 (19.3)	130 (20)
	n=1,384	n=645
Ever	619 (44.3)	293 (45.1)

[¶)] heavy phys work: long-term, much lifting and bending. [§)] Women whose last menstruation occurred at least one year previously [*)] Due to missing data percentages do not always correspond with the total group

PFMF and the POP symptom of vaginal bulging

Table III presents the different determinants of PFMF associated with symptomatic and asymptomatic POP in women who had a vaginal examination. There were no significant differences in any of the PFMF items between women with and women without POP symptoms, except for voluntary relaxation of the PFM that had a significant score (0.011). More women who were asymptomatic for vaginal bulging had incomplete voluntary relaxation scores (21.1% versus 11%).

Table III Pelvic floor muscle function in numbers (percentages) in women who were symptomatic or asymptomatic for POP symptoms

	response	Symptomatic for POP (n=79)	Asymptomatic for POP (n=569)	p value
Visual inspection				
co-contraction visible	yes	26 (33.8)	194 (34.8)	.486
	no	51 (66.2)	364 (65.2)	
incontinence during coughing	yes	9 (11.4)	47 (8.4)	.244
	no	70 (88.6)	513 (91.6)	
Palpation during voluntary muscle contraction				
urethral lift	yes	45 (60)	342 (63)	.352
	no	201 (37)	201 (37)	
inward movement perineum	yes	63 (81.8)	420 (76.2)	.230
	no	14 (18.2)	126 (22.9)	
	downward	0	5 (0.9)	
levator closure	yes	45 (59.2)	337 (62.3)	.345
	no	31 (40.8)	204 (37.7)	
voluntary relaxation	good	47 (64.4)	259 (49.7)	
	delayed	18 (24.7)	152 (29.2)	.011
	incomplete	8 (11)	110 (21.1)	
voluntary contraction	absent	4 (5.1)	29 (5.2)	.592
	weak	26 (32.9)	175 (31.3)	
	normal	47 (59.5)	326 (58.2)	
	strong	2 (2.5)	30 (5.4)	
endurance	0-10 sec	6.25 (3.11)	6.25 (3.31)	
Palpation during involuntary muscle contraction while coughing				
downward movement perineum	yes (ineff. IMC)	41 (51.9)	291 (52)	.543
no downward movement perineum	no (eff. IMC)	38 (48.1)	269 (48)	
Palpation during involuntary muscle relaxation while straining				
caudal perineal movement during straining	yes	73 (93.6)	493 (89.5)	.177
no caudal movement	no	5 (6.4)	58 (10.5)	

PFMF versus POPQ

Table IV presents the POPQ stage versus the different PFMF items. All the determinants of PFMF in the women with stage 1-4 POP were compared to those in the women without POP and tested for significance. POP prevalences per stage were 25% (161) for stage 0, 36.5% (235) for stage 1, 33% (212) for stage 2, 5% (32) for stage 3 and 0.5% (3) for stage 4.

Significant differences were found in the caudal movement of the perineum during straining. Women with the lower stages of POP were less able to perform the proper straining technique than the women with ≥ stage 2. Visible co-contractions, incontinence during coughing and levator closure also differed significantly between the groups (p=.001). POP stage had a significant influence on effective involuntary PFM contraction (IMC) to counteract a sudden increase in intra-abdominal pressure (IAP) during coughing (75.2% in stage 0 versus 38.3% in stage 1 and 37.7% in stage 2).

Table IV Association between pelvic floor muscle function and pelvic organ prolapse (measured with the POPQ) in numbers (percentages)

	outcome	PFMF versus vaginal examination					
		stage 0	stage 1	stage 2	stage 3	stage 4	p value*
Visual inspection							
co-contraction visible	yes	41 (25.8)	83 (35.5)	85 (40.3)	10 (31.3)	3 (100)	.006
	no	118 (74.2)	151 (64.5)	126 (59.7)	22 (68.8)	0	
incontinence during coughing	yes	2 (1.2)	22 (9.4)	29 (13.7)	2 (6.3)	3 (100)	<.001
	no	159 (98.8)	213 (90.6)	183 (86.3)	93.8 (30)	0	
Palpation during voluntary muscle contraction							
urethral lift	yes	109 (69)	145 (63.6)	116 (56.9)	17 (58.6)	1 (33.3)	.013
	no	49 (31)	83 (36.4)	88 (43.1)	12 (41.4)	2 (66.7)	
inward movement perineum	yes	122 (76.7)	182 (78.4)	153 (74.6)	24 (77.4)	2 (66.7)	.495
	no	37 (23.3)	48 (20.7)	49 (23.9)	7 (22.6)	1 (33.3)	
	downward	0	2 (0.9)	3 (1.5)	0	0	
levator closure	yes	122 (77.2)	147 (65)	100 (49)	16 (53.3)	0	<.001
	no	36 (22.8)	79 (35)	104 (51)	14 (46.7)	3 (100)	
		n=150	n=219	n=195	n=31	n=3	
voluntary relaxation	good	67 (44.7)	116 (53)	51.8 (101)	64.5 (20)	66.7 (2)	.088
	delayed		51 (23.3)	31.8 (62)	12.9 (4)	33.3 (1)	
	incomplete	31 (20.7)	52 (23.7)	16.4 (32)	22.6 (7)	0	
		n=161	n=235	n=211	n=32	n=3	
Maximum voluntary contraction	absent	8 (5)	14 (6.0)	5.7 (12)	0	0	.280
	weak	53 (32.9)	61 (26)	35.5 (75)	37.5 (12)	66.7 (2)	
	normal	91 (56.5)	145 (61.7)	55.5 (117)	62.5 (20)	33.3 (1)	
	strong	9 (5.6)	15 (6.4)	3.3 (7)	0	0	
		n=161	n=234	n=212	n=32	n=3	
mean endurance in seconds	0-10 sec	6.51 (SD 3.2)	6.35 (SD 3.39)	5.93 (SD 3.25)	6.28 (SD 3.15)	4.00 9SD 1.00)	
Palpation during involuntary muscle contraction while coughing							
downward movement perineum	no, meaning effective IMC	121(75.2)	90 (38.3)	80 (37.7)	20 (62.5)	0	<.001
downward movement perineum	yes, meaning neffective IMC	40 (24.8)	145 (61.7)	132 (62.3)	12 (37.5)	0	
Palpation during involuntary muscle relaxation while straining							
caudal perineal movement during straining	yes	127 (80.4)	210 (90.5)	199 (95.7)	30 (93.8)	3 (100)	<.001
no caudal movement	no	31 (19.6)	22 (9.5)	9 (4.3)	2 (6.3)	0	

* *Statistical comparison by Chi-square test for trend, except for mean endurance in seconds: F-test from ANOVA*

Discussion

This was the first study that tested PFMF in relation to POP in a general female population. We found a significant difference in effective IMC to counteract sudden increases in IAP during coughing between the women without POP and those with different stages of POP. It is difficult to explain why there was such an enormous decrease in the ability to resist IAP in the women with stage 1 POP. Future research should address whether this decrease is a contributing factor to the development of POP.

The item PFMF levator closure during VMC demonstrated significant differences between the POP stages. We know that part of the process of POP development is widening of the genital hiatus [16] and if we combine that with the weak ability to perform levator closure with VMC and ineffective IMC during an increase in IAP, then the result could lead to POP.

It is a well-recognized physiological process that during physical activities, people hold their breath and stabilize their diaphragm to create greater strength and consequently, a strong increase in IAP. PFM are reflexly activated during any stress. This activation is preset in particular motor patterns such as coughing and is not just a reflex response to increased IAP.[17] Such increases in IAP are present not only during heavy lifting or sports, but also in daily activities and they require optimal IMC. However, nobody consciously learns to contract their PFM to counter this increasing IAP, which might therefore lead to PFD. Especially appear women to be at risk.

Our study revealed that muscle strength and endurance were not significantly different between the POP stages. This supports the assumption that muscle strength and endurance are not the only key issues in the design of new treatment strategies or preventive measures for POP, because even if they are optimal, they do not seem to prevent POP completely.

No significant differences in PFMF were found between the women who reported that they were symptomatic for vaginal bulging and those without these symptoms, except for relaxation after VMC. In one of our earlier publications of the vaginal examination revealed that only 30.7% of the women with clinically relevant POP were symptomatic.[18] This might explain the lack of significant differences in PFMF between the symptomatic group and the asymptomatic group.

Several recommendations can be made for POP treatment and preventive measures based on our study results. Apparently, strong PFM alone does not seem to prevent the development of POP. However, we must be careful drawing these conclusions due to the character of this study. To study the effect

of PFM training on the prevention and treatment of POP, Bo [19] reviewed basic research and case-control studies and put forward two hypotheses: 1) women can learn to contract their PFM consciously before and during an increase in IAP and will continue to make such contractions as a behavioural modification in order to prevent descent of the pelvic contents and 2) women can learn to build up 'muscle tone' and structural support of the pelvic floor through regular strength training over time. Owing to the lack of high quality randomized controlled trials on the effect of PFM training in women with POP, neither of the hypotheses could be confirmed. Longitudinal studies are necessary to provide reliable evidence. Some women might achieve greater PFM strength and endurance as a direct reaction to the development of POP, whereas others might experience deterioration in PFMF due to the progression of POP. It seems that good coordination of the PFM, as demonstrated by effective IMC, is more important. Normal or strong VMC and good PFM endurance do not guarantee effective IMC of the PFM [Slieker et al., 2009 PFMF in general population, submitted IUJ]. Therefore, clinicians should test VMC and IMC to gain insight into a woman's ability to counteract any sudden increase in IAP.

Based on the results of the present study, the inclusion of effective IMC of the PFM in new treatment plans seems promising, as was shown in the recent study by Hagen et al.[8], in which women with stages 1 and 2 POP were treated effectively with a protocol that included greater awareness of the location of the PFM and the importance of pre-contraction before an IAP increase, for example when coughing or lifting. In daily practice, it will be challenging to recruit women without POP and women with stage 1 so that PFM awareness and training can be started at an early stage in the form of preventive measures. In a recent study, a new combination of risk factors was identified, namely vaginal bulging during pregnancy, a family history of POP and heavy physical work. The first steps are the organization of antepartum or postpartum training groups and 'POP-prevention-groups' for women at risk.

Some reservation must be taken into account when making assumptions about the effect of PFM training to prevent the development or progression of POP. Postpartum MRI and ultrasound studies have demonstrated asymmetrical damage, avulsions and abnormalities of the pelvic floor.[20-21] As the pelvic floor is primarily seen as a functional unit (that combines the closure system of the excretory tracts, support system for the pelvic viscera and a participating unit in the sexual response) it does not seem to be possible to activate the right half or left half of the PFM separately, or to strictly separate activation of individual pairs of muscles.[17, 22] Therefore, it would be worthwhile to study the effect of PFM training in women with asymmetrical

damage, in relation to the prevention of POP or other symptoms of pelvic floor dysfunction.

Strengths and limitations

A strength of our study was the ethnic homogeneity, because almost all of the women were white, which eliminated racial bias from the results. Furthermore, broad data were obtained from a large general study group using a combination of questionnaires and vaginal examination. However, despite the high compliance, selection bias can never be excluded. Another limitation was the lack of blinding of the assessors for the POPQ results. This might cause some bias. However, we regard this possible bias not as a major problem since a) no interpretation of the results was made during the assessment and b) the findings of this study were not hypothesized prior to the study. Another remark can be made regarding the assessment scheme used. Although face validity and reliability of the assessment scheme was tested prior to this study only one study supports the use of this assessment of pelvic floor muscle function. We would recommend further research to demonstrate the value of this assessment scheme in larger populations. This study was performed on a general population of mainly white women (98%) with a mean BMI of 25. Therefore, extrapolation to other populations has to be performed with caution.

Conclusions

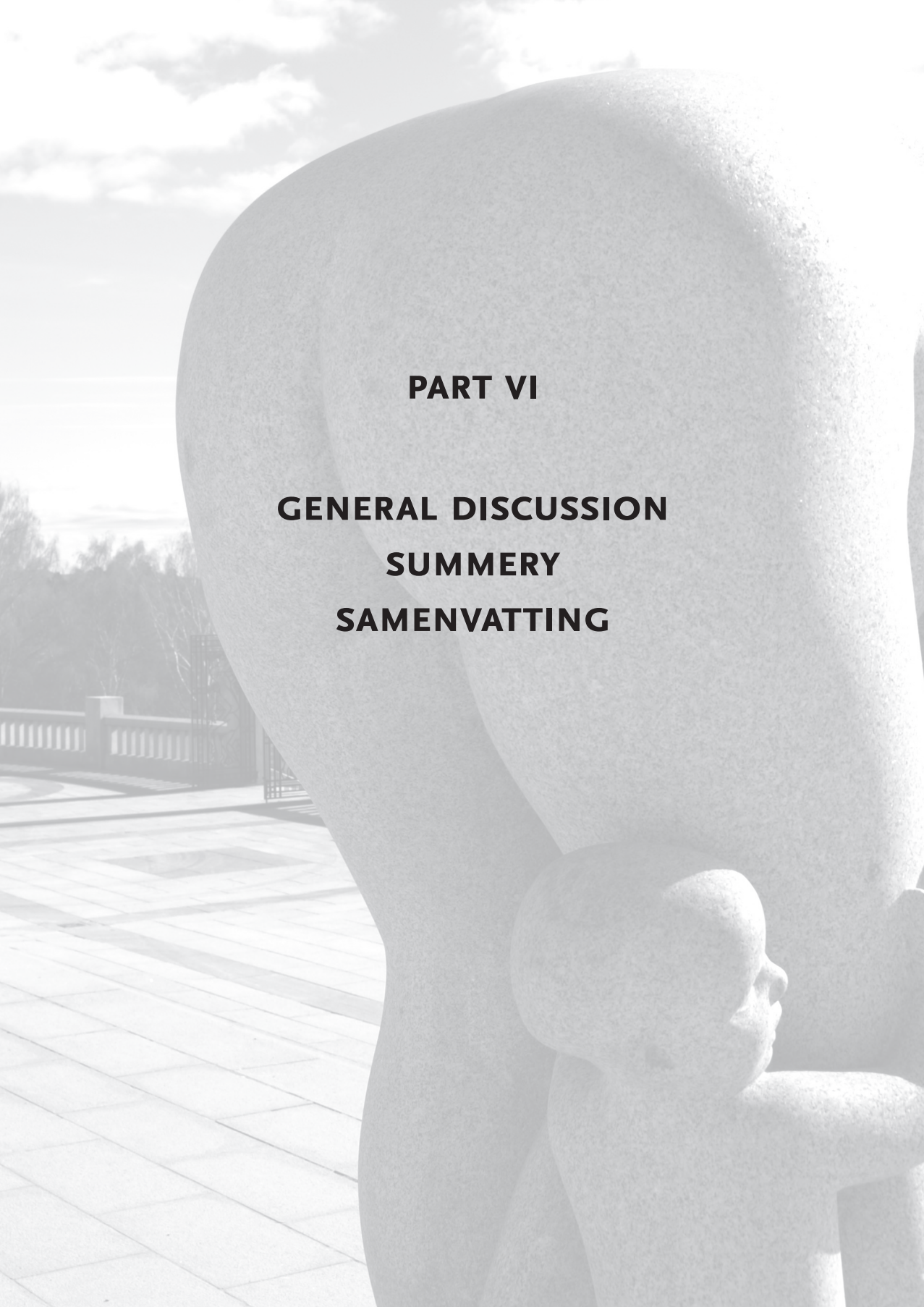
Women with POP lacked effective IMC of the PFM. More knowledge is needed on the role of PFM training in prevention of POP and the pathogenesis of POP.

References

1. Swift SE, Tate SB, Nicholas J. Correlation of symptoms with degree of pelvic organ support in a general population of women: what is pelvic organ prolapse? Am J Obstet Gynecol 2003 189(2):372-377; discussion 377-379.
2. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997 89(4):501-506.
3. Subak LL, Waetjen LE, van den Eeden S, Thom DH, Vittinghoff E, Brown JS. Cost of pelvic organ prolapse surgery in the United States. Obstet Gynecol 2001 98(4):646-651.
4. DeLancey JO. The hidden epidemic of pelvic floor dysfunction: achievable goals for improved prevention and treatment. Am J Obstet Gynecol 2005 192(5):1488-1495.
5. Chen L, Ashton-Miller JA, Hsu Y, DeLancey JO. Interaction among apical support, levator ani impairment, and anterior vaginal wall prolapse. Obstet Gynecol 2006 108(2):324-332.

6. Slieker-Ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. Symptomatic pelvic organ prolapse and possible risk factors in a general population. Am J Obstet Gynecol Feb;200(2):184.e1-7. Epub 2008 Dec 25
7. Vakili B, Zheng YT, Loesch H, Echols KT, Franco N, Chesson RR. Levator contraction strength and genital hiatus as risk factors for recurrent pelvic organ prolapse. Am J Obstet Gynecol 2005 192(5):1592-1598.
8. Hagen S, Stark D, Glazener C, Sinclair L, Ramsay I. 2009. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct 20(1):45-51.
9. Borello-France DF, Handa VL, Brown MB, Goode P, Kreder K, Scheufele LL, Weber AM. Pelvic-floor muscle function in women with pelvic organ prolapse. Phys Ther 2007 87(4):399-407.
10. Messelink B, Benson T, Berghmans B, et al. Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn 2005;24:374-80.
11. Slieker-Ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. Face validity and reliability of the first digital assessment scheme of pelvic floor muscle function conform the new standardized terminology of the International Continence Society. Neurourol Urodyn.28(4):295-300.
12. Edwards, P, Roberts, I, Clarke, M, Diguiseppi, C, Pratap, S, Wentz, R, et al. Increasing response rates to postal questionnaires: systematic review. Bmj 2002;324:1183.
13. Van Der Vaart, CH, De Leeuw, JR, Roovers, JP, Heintz, AP. [The influence of urinary incontinence on quality of life of community-dwelling, 45-70 year old Dutch women] De invloed van urine-incontinentie op de kwaliteit van leven bij thuiswonende Nederlandse vrouwen van 45-70 jaar. Ned Tijdschr Geneeskd 2000;144:894-7.
14. Van Brummen, HJ, Bruinse, HW, Van De Pol, G, Heintz, AP, Van Der Vaart, CH. Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. Int Urogynecol J Pelvic Floor Dysfunct 2006;17:224-30.
15. Bump, RC, Mattiasson, A, Bo, K, Brubaker, LP, Delancey, JO, Klarskov, P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10-7.
16. Schaffer JI, Wai CY, Boreham MK. Etiology of pelvic organ prolapse *Clin Obstet Gynecol*. 2005 Sep;48(3):639-47
17. Deindl FM, Vodusek DB, Hesse U, Schussler B. Activity patterns of pubococcygeal muscles in nulliparous continent women, Br J Urol 1993;72-51.
18. Slieker-Ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME (2009. Prediction model and prognostic index to estimate clinically relevant pelvic organ prolapse in a general female population. Int Urogynecol J pelvic Floor Dysfunct May 15
19. Bo K. 2006. Can pelvic floor muscle training prevent and treat pelvic organ prolapse? Acta Obstet Gynecol Scand 85(3):263-268.

20. DeLancey JO, Kearney R, Chou Q, Speights S, Binno S. 2003. The appearance of levator ani muscle abnormalities in magnetic resonance images after vaginal delivery. Obstet Gynecol 101(1):46-53.
21. Dietz HP, Gillespie AV, Phadke P. 2007. Avulsion of the pubovisceral muscle associated with large vaginal tear after normal vaginal delivery at term. Aust N Z J Obstet Gynaecol 47(4):341-344.
22. Vereecken RL. Derluyn J, Verduyn H. electromyography of the perineal striated muscles during cystometry. Urol Int 1975;30:92-98.



PART VI

GENERAL DISCUSSION
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Chapter 12
General discussion

General discussion

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, which 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 important to focus on the different aspects of the pelvic floor and the pelvic organs, before combining these elements into a functional diagnosis. One of the challenges is to identify risk factors and causes for the different dysfunctions, in order to promote work on prevention and/or best options for diagnosis and treatment. The current lack of knowledge emphasizes the importance of pelvic floor studies to gain more insight into the pathophysiology of PFD.

Over the past 20 years, a great deal of attention has been paid to urinary and faecal incontinence [4-5] in terms of their pathophysiology, assessment and conservative treatment [6], surgical treatment [7-9] and the use of medication.[10-11] The International Consultation of Incontinence (ICI) have made dedicated efforts to standardize the assessment and treatment of incontinence.[12] Furthermore, many initiatives have been taken to raise public awareness about incontinence. For instance, the World Continence Week, initiated by the International Continence Society (ICS), is an excellent and highly necessary example of this.

Contrastingly, attention to the pathophysiology of pelvic organ prolapse (POP) has mainly focused on diagnosis, pessary use and surgical treatment [13], but not on conservative treatment.

In this general discussion, we discuss the following results: 1) the prevalence of PFDs, such as urinary, faecal and double incontinence, 2) the prevalence of POP symptoms (measured using a questionnaire) and risk factors for POP, 3) the prevalence of POP signs (measured by vaginal examination), 4) a predic-

tion model for clinically relevant POP, 5) the prevalence of vaginal noise, 6) assessment of the pelvic floor musculature (PFM) 7) the prevalence of PFM function in a general female population and 8) the relation between POP and PFM function.

Incontinence

We found that 62.5% of our general female population aged 45-85 years had some form of incontinence and that 10.3% were suffering from double incontinence (i.e. liquid and/or solid stool incontinence and urinary incontinence). When this double incontinence was extended to include flatal incontinence, the latter rate increased to 35.4%. (see Chapter 7). Quality of life, measured with the EuroQol, was significant lowetr in the women with incontinence, especially in those with double incontinence than in continent women. Especially from the women with double incontinence the quality of life, in whom we measured the EuroQol, was significantly lower compared to the continent women.

Fortunately, many successful treatment options are available: conservative treatment by a pelvic floor physiotherapist, which has become accepted as the first option of treatment, besides surgery and medication.[14]

Analysis of urinary incontinence in relation to anal incontinence revealed a significant association between urge urinary incontinence (UUI) and liquid stool incontinence and solid stool incontinence, with risk estimates of 4.3 and 4.9, respectively (see Chapter 7).

The association between irritative bladder symptoms (overactive bladder and interstitial cystitis) and *urge anal* incontinence in women with AI is of extreme interest, because it supports the view that a common visceral mobility disorder plays a role in DI.[15] The reason for this combination of symptoms is not yet clear, although Shafik et al. described vesico-anal reflexes [16] and Leroi et al. drew attention to the effect of neuromodulation on UUI as well as on faecal incontinence.[17]. Blok [18] demonstrated that there are continence and micturition centres in the brain stem. As yet, no defaecation centre has been found, but it is likely that there is a similar control centre as that for micturition.

Although faecal incontinence causes enormous bother, women with faecal incontinence were less inclined to consult their physician than women with urinary incontinence, due to the taboo surrounding faecal incontinence.[19] Therefore, we strongly recommend that when physicians take the history of women with UUI or mixed urinary incontinence (MUI) they always include questions that focus on the possible co-existence of any form of AI. It should also be realized that only a relatively small number of women seek help for

their bladder and bowel disorders, which underlines the necessity to expand public awareness programmes.

Pelvic Organ Prolapse (POP)

In contrast with the extensive attention being paid to bladder and bowel disorders as part of PFDs POP has received a different type of attention, because a conservative approach is hardly ever offered as first treatment option. For many years, POP was only viewed as a PFD caused by laxity of the connective tissue and ligaments. Hardly any of the literature discussed the function of the pelvic floor musculature (PFM) or possible conservative treatment for POP until we presented our first results on PFMF and POP on the ICS-IUGA conference in 2004 [Distribution of Pelvic Organ Prolapse (POP) in the general population; prevalence, severity, aetiology and relation with the function of the pelvic floor muscles. [Abstract 4, ICS-IUGA 2004, Paris, www. icsoffice.org]. Many studies demonstrated the effect of different types of surgery, whereas in contrasting articles, we read that when POP was not symptomatic enough, or POP was not clinically relevant, the women received verbal reassurance, but no treatment was offered except for an occasional pessary (see Chapter 4). However, POP should be regarded as either a cause of PFD, or a consequence of it. Fortunately, an increasing number of studies have focused on the pathophysiology of POP.[20-21] Owing to the complexity of the pelvic floor (muscle layers, ligaments, connective tissue, etc.) it is important to establish the exact location of the damage and to identify which specific risk factors apply to which anatomical elements. With this knowledge, we will be able to improve our search for preventive measures.

The main focus of this thesis was on POP and our first aims were not only to study the prevalence of POP symptoms, but also to identify (new) risk factors in a general female population (see Chapter 4).

Many POP-related symptoms have been described, such as urinary splinting, abdominal heaviness, incontinence, digital support in defaecation, low back pain or vaginal bulging. In the literature, only the latter symptom was addressed by two questions specifically directed at POP and was found to have the highest predictive value of 81% for POP.[22] Therefore, we used these two questions to study the prevalence of POP symptoms (Do you feel a vaginal bulge and/or do you see a vaginal bulge?).

The prevalence of POP symptoms in our study was 11.4%. This is comparable with the rates reported in other general population studies.[23-25] In our search for risk factors, we hoped to find new risk factors, because the previously demonstrated risk factors for POP, such as parity, genetic factors, age

[26-29] etc., cannot be modified and are therefore irrelevant in the development of preventive strategies.

In our study, the most important finding was that a combination of three risk factors led to a population attributable risk (PAR) of 46%. This means that out of every 100 women with POP, 46 can be explained by the following three factors: feeling and/or seeing vaginal bulging during pregnancy, a mother with POP and heavy physical work. Although genetic factors and pregnancy complications cannot be modified, this study demonstrated that it is possible to identify women at risk for POP at a very early age. When a woman has a mother with POP and has suffered from vaginal bulging during pregnancy, she needs to become aware that heavy physical work must be avoided and that pelvic floor physiotherapy could be an option to obtain instructions and to learn not *'to lift anything more than her pelvic floor can withstand'*. As part of being a young mother involves lifting children, baby baths, doing quick supermarket shopping and training abdominal muscles to regain her old figure etc., we must raise awareness of the risk of POP in these women and also teach mothers to educate their daughters.

Pelvic organ prolapse quantification

Owing to the fact that the subjective symptoms of POP in the patient are not always the same as the clinical signs observed by the physician, the next aim of our study was to compare the answers to the questionnaires to the results of vaginal examination (see Chapter 5). To measure POP, we used the pelvic organ prolapse quantification (POPQ). The POPQ was developed by Bump et al. and has been accepted in the standardization of the ICS.[30] However, in the literature and clinical practice, we still need to answer the question of 'What is the definition of clinically relevant POP? It has been hypothesized that POP gives rise to complaints when the prolapse has reached or passed the hymen. However, in stage 2, it is clinically difficult to judge the level, because the definition of stage 2 is that POP is located 1 cm above the hymen to 1 cm beyond the hymen. Furthermore, a discrepancy exists in the literature between feeling and/or seeing vaginal bulging as a cornerstone symptom of POP and the presence of POP signs. For these reasons, we devised three new cut-off points within stage 2 and found that POP 'at or beyond' the hymen had the most significant relation with the POP symptoms. Clinically relevant POP is therefore defined as symptomatic POP 'at or beyond the hymen'. In our study group, 17.5% had clinically relevant POP.

Our aim was to develop a prediction model that could be used in research to estimate the prevalence of clinically relevant POP in large general female populations, without the need for vaginal examination (see Chapter 5). This prediction model was based on 17 questions.

The Receiver Operating Characteristics (ROCs) of the multivariate analysis showed Areas under the Curve (AUC) of 0.72 and 0.76. A shrinkage factor of 0.63, estimated from the bootstrap validation procedure, was applied to his model to enable optimal predictive performance with substantial sensitivity and specificity.

To adapt the prediction model for use in future studies, we developed a simple POP-Score-Chart with a prognostic index to estimate the presence of clinically relevant POP in a general female population, without the need for vaginal examination. The Score Chart may also help women to estimate the severity of their POP and whether they should consult a physician. Greater awareness of the potential presence of POP and personal risk factors will encourage women to seek advice about how to deal with their symptoms.

When we analysed the prevalence of POP stage 0-4 in relation to vaginal bulging (n=79), the symptom of vaginal bulging was present in 42.8% of the women with stage 2 (33/79) and in 20.8% of those with stage 3 and stage 4 (16/79). On the other hand, in the group of women without POP and in those with a mild stage (stage 0 and 1) 15.6% and 20.8% had positive scores on the symptom of vaginal bulging, respectively. Although other studies reported very similar results, the exact reason for this discrepancy between signs and symptoms is still obscure. Until we know the reason, it will be very difficult to treat this group of women. We hypothesize that issues in the personal sphere, such as coping strategies, attitudes and beliefs or socio-economic factors, play a role. In any case, pelvic floor muscle function needs to be studied closely as well. All these factors must be taken into account in the search for methods to increase awareness of PFD and to develop preventive strategies.

We recommend that future research focuses on these personal and socio-economic factors in relation to POP and the role of the PFMF. However, some caution must be applied when drawing firm conclusions on the basis of the POPQ itself, which became clear in our later comparison between the POPQ stages and the anatomic location.

Vaginal bulging, POPQ stages and bladder and bowel disorders

The next aim was to investigate whether there were relations between POP symptoms (measured using a questionnaire), POP signs (measured during vaginal examination (POPQ)) and symptoms of existing bladder and bowel disorders (see Chapter 6). Currently, it is the general trend to blame many bladder and bowel disorders on POP.

Although the POPQ is well-accepted in uro-gynaecological research, our analysis did not demonstrate any significant relation between the POPQ

stages and the different bladder and bowel symptoms, except for the obvious symptom of vaginal bulging. This was surprising, because in other studies, urinary incontinence was found to be related to the lower POP stages I and II.[14] However, within the ordinal stages 0-4, no information is given about whether the anatomical location, anterior or posterior, is responsible for a particular stage. This explains why the POPQ score alone is not sensitive enough to demonstrate relations with bladder and bowel disorders. Analysis of the anatomical location of the POPQ, noted in the nine-point grid (Aa, Ba, C, D, Ap, Bp, PB, GH and TVL) yielded more information: the most dependent portion of the lowest point of the upper vaginal wall was significantly associated with urge urinary incontinence (UUI). This finding supported an earlier study in which the UUI disappeared after successful surgical correction of the vaginal wall.[31] However, de novo UUI after vaginal wall correction has also been described.[32] The following question remains: can changing the anatomical condition of the anterior wall trigger the bladder wall in some way and result in UUI? We are already aware of the existence of vesico-anal reflexes and cough anal reflexes.[16,33] Do more factors play a role in the development of UUI after surgery? And we can postulate further: does the posterior vaginal wall play any role after anterior vaginal wall surgery?

Another related and important finding was the strong association between obstructive bowel disorders and the position of the posterior compartment. This can partly be due to anatomical changes in the posterior wall, but a more functional cause must be also considered, such as slow transit of the bowel or loss of sensibility in the rectum. After surgical correction of the posterior vaginal wall, the mechanism that outlet obstructed defaecation did not always disappear, which could mean that more functional elements are involved.[34] Every woman is afraid to defaecate after vaginal surgery which may lead to the development of incorrect defaecation techniques that influence bladder function. It is also relevant to avoid constipation as much as possible, especially in combination with the above-mentioned risk factors. There seems to be a delicate balance in the pelvic floor that can be influenced by muscle awareness. Thus, many PFDs might benefit from conservative treatment and very careful planning of pelvic floor surgery, because once the balance has been disturbed, it may not be regained. Should surgery been seen as the last treatment option?

Vaginal noise

The next isolated symptom of PFD that we studied was vaginal noise. Data were gathered on prevalence, the amount of bother it was causing and risk factors for its development (see Chapter 8), because it is often present, but seldom reported as a symptom of PFD. In our study, 12.8% of the population

reported vaginal noise, but 72.1% of them indicated that it was only causing a little bother.

In a study by Krissi [35] on pelvic floor muscle strength assessment, no significant differences were found between the symptomatic and asymptomatic women. The PFM training that was given to the six patients they described did not have positive effects. For this reason, we included PFMF assessment in the analysis. In our support of Krissi's study, we did not find any significant difference in PFMF outcome between the symptomatic group and the asymptomatic group. Therefore, we assume that PFMF is not the first or most important factor in the aetiology of vaginal noise. Nevertheless, we demonstrated high odds ratios for parity and solid stool incontinence on vaginal noise. The only significant anatomical relation was between the lowest point of the upper posterior wall, which once again draws attention to the posterior vaginal wall.

Assessment of pelvic floor muscle function

As a physiotherapist, my greatest interest is in the role of the 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. In recent years, PFMF has been playing a central role in the treatment of stress urinary incontinence and high quality randomized controlled trials have been performed by many research groups.[36] Since the introduction of Kegel exercises, different assessment scales have been developed and over the past decade, three different assessment scales have become popular, particularly the Laycock PERFECT assessment scale that assesses muscle strength, endurance and exhaustion.[37] One of the other assessment scales, developed by Brink et al., assesses three different items: urethral lift, muscle strength and muscle endurance, but endurance is only tested for three seconds, which in the opinion of physiotherapists, is far too short.[38] These two assessment scales only used voluntary muscle contraction (VMC) to test all the different items. Thus, especially levator closure, effective involuntary contraction (IMC) during coughing and involuntary relaxation during straining were missing. In 2004, Devreese et al. proposed a new assessment scale and introduced more coordinative items, but these coordinative items were defined as coordination between the PFM and abdominal muscles.[39] Research has also been performed into PFMF in relation to the stability of the pelvis [40] and in relation to the abdominal muscles and their roles in postural control [41], but once again, IMCs were missing. Therefore, PFMF assessment needed to be reviewed.

Fortunately, in 2005, the Clinical Assessment Group on PFM within the ICS (PFCAG) introduced new terminology on PFMF and for the first time,

besides many other items, this included effective IMC to resist sudden increases in IAP during for example coughing.[42] However, at the time of our study, this terminology had not yet been transformed into an assessment scale. Thus, our next step was to create an assessment scale based on this terminology (see Chapter 9). As the outcome measures were not well-defined, many Delphi rounds were needed to devise strictly defined outcome measures. Face validity and intra-observer reliability were satisfactory, but inter-rater reliability was low. The latter naturally had consequences on our study. More modifications needed to be done on the present scale and therefore, the two examiners of this study put a great deal of effort into training with the protocol until they achieved the same scores.

Pelvic floor muscle function in a general female population

Before studying possible relations between PFMF and POP, we measured PFMF in a general female population. An interesting secondary issue was to test whether assessments of muscle strength and muscle endurance alone were informative/sensitive enough to diagnose the status of the total PFMF (see Chapter 10), because in clinical practice, the decision of whether or not to refer the patient for pelvic floor physiotherapy is based on muscle strength and sometimes muscle endurance. Muscle strength and muscle endurance in relation to the other PFMF items were largely as we expected: strong PFM and good endurance (tested with voluntary muscle contraction (VMC)) were related to better functioning of other items, such as urethral lift and levator closure. Strong PFM and good endurance were also related to decreased co-contractions, which seemed to guarantee effective VMC of the PFM. The only significant exception was involuntary muscle contraction (IMC) during coughing: the women with normal or strong PFM were even less able to achieve effective IMC than the women with weaker PFM. This was an interesting finding, because during the past ten years of PFMF assessment, only VMCs have been used to test awareness of the PF muscle strength, muscle endurance, timing and urethral lift.[37-38] Our analysis demonstrated that the information gained in this way is not enough to diagnose total PFMF.

The last step of our study was to test PFMF in relation to POP, while taking the above-mentioned findings into account.

Pelvic floor muscle function in relation to pelvic organ prolapse

In our total study population 46.4% of the women filled in the questionnaire and underwent vaginal examination. We hypothesized that women with weak or absent muscle strength and muscle endurance have more severe POP than women with strong or normal PFMF. However, we could not confirm this hypothesis. A surprising significant difference was found in effective invol-

untary muscle contraction (IMC): 75.2% of the women without POP were able to resist the increased intra-abdominal pressure (IAP) compared to only 38.3% with stage 1, which is remarkable, because generally, these two stages are asymptomatic. It was even more surprising that we could not demonstrate any significant differences in urethral lift, muscle strength and muscle endurance (tested with voluntary muscle contraction (VMC)) between the POP stages (see Chapter 11). These results support the assumption that muscle strength and muscle endurance are not crucial elements in the design of new treatment strategies or preventive measures for POP, because even if they are optimal, they do not seem to protect against the development of POP.

The key issue was that the women without POP could resist a sudden increase in IAP during coughing far better than the women with mild POP. Why there was such an enormous decrease in the ability to resist IAP in the women with stage 1 is difficult to explain. Whether this decrease contributes to the development of POP is not clear either and should form the subject of future research.

Strengths and limitations of the study

One of the major strengths of this study was the use of vaginal examination to obtain data from a large population of women in a cross-sectional design. POP prevalence varies between different ethnicities.[43] Another strength of our study was the ethnic homogeneity, because almost all of the women were white, which eliminated racial bias from the results. Furthermore, broad data were obtained using a combination of questionnaires and vaginal examination.

Our data revealed important associations between different PFDs and POP that will help to support the development of preventive strategies for pelvic floor disorders.

This was the first study to analyse the relation between POP and PFMF.

This study also had limitations. The 98% white race in our population may have negative effects on extrapolation to other general populations. In addition, the questionnaire contained a long list of enquiries and the vaginal examination obviously formed a burden on the women who took part. A questionnaire can elicit socially desirable answers, although this was probably minimal, due to the anonymity of the responses to the questionnaires. It is often difficult to identify POP, because the situation can change over the course of the day and there is considerable dependence on performing a maximum Valsalva manoeuvre. Selection bias might have caused the differences in outcome due to the homogeneity of the study population (98% white) or because women with POP symptoms were more likely to agree to

undergo vaginal examination, which could have caused overestimation of the real prevalence of POP.

Implementation
An important finding in this study was that POP risk can be identified in a very early phase of life, i.e. when a woman is pregnant. However, it will be challenging to actually identify women who are at risk before they become symptomatic. We demonstrated a significant decrease in the PFMF item effective IMC during coughing, but we also observed that the women without POP were mostly asymptomatic. To help women to raise awareness and take the various risk factors into account that can support the women to seek help, we developed a simple-to-use POP score chart (see Chapter 5).

As women visit prepartum and postpartum classes during and after pregnancy, pelvic floor physiotherapists need to increase their awareness. Special Pelvirobics® have been developed that present a fitness programme for (ex)-patients with low back, pelvis and pelvic floor disorders that include information on risk factors and PFM awareness related to low back and pelvic pain.

Future research
To gain insight into the effect of PFM training on the prevention and treatment of POP, longitudinal studies need to be performed on the effect of PFM training, including its effect on IMCs during increases in IAP. Further attention should be paid to the second hypothesis formulated by Bo in her research, i.e. that regular strength training is enough to build up stiffnes in the pelvic ring and structural support of the pelvic floor.[44] Perhaps this approach can be included in randomized clinical trials. Also future studies should include more varied ethnicity.

A recent study by Hagen et al.[45] has emphasized the importance of including effective IMC into a PFM treatment plan. Their study showed that the effect of PFM training is promising because women with stages 1 and 2 were treated effectively with a protocol that included boosting their PFM awareness and the importance of pre-contraction before IAP increases, for example, coughing and lifting. In daily practice, it will be challenging to identify women with stages 0 and 1 so that PFM awareness and training can be started in an earlier enough phase to prevent POP. However, there is an urgent need for more data.

Some reservations must be taken into account when making presumptions about the effect of PFM training to prevent the development or progression of POP. Postpartum MRI and ultrasound studies have demonstrated asym-

metrical damage, avulsions and abnormalities of the pelvic floor.[19-20] As the pelvic floor is primarily seen as a functional unit (that combines the closure system of the excretory tracts, support system for the pelvic viscera and a participating unit in the sexual response) it does not seem to be possible to activate the right half or left half of PFM separately, or to strictly separate activation of individual pairs of muscles.[46-48] Therefore, it is important to research the effect of PFM training in women with severe asymmetrical damage to the PFM.

Closing remarks

This study was performed on a general population of women aged 45-85 years, living in the Dutch town of Brielle, the Netherlands. When vaginal examination forms part of a research project, it is often difficult to perform these studies. They are time-consuming and expensive and are therefore mostly performed on selected populations, e.g. women visiting the uro-gynaecological clinic for a yearly check-up [49], or women who are receiving hormone replacement therapy.(50)

We wholeheartedly agree with Swift who, in one of his studies on women visiting the outpatient gynaecology clinic, remarked that the evaluation group had a variety of complaints, but one commonality: they all required pelvic examination as part of routine gynaecological health care. Although the women probably represented a typical population of gynaecology outpatients, he stated not to assume that they represented the general population as a whole.

> *'Attempting to identify a population of subjects that accurately reflects the general population of women in this country is difficult at best and may be impossible, particularly if participation in the study requires that the subject undergo a pelvic examination'.* [51]

We are therefore very very grateful to all the women from Brielle who agreed to participate in the vaginal examination in our study.

Public awareness

Although we were aware that a large number of women suffer from PFDs, we ware surprised that only 10% were negative on all the PFD symptoms.

Whereas extensive public information/advertisements are available in newspapers, on the television and internet on, for example, the prevention of COPD, heart disease, high blood pressure, breast cancer, osteoporosis, or falls in the elderly, no public information is given about POP. Beside an atmosphere of taboo in the journalism, other possible reasons for this are that older women and their problems are not considered to be important enough, women with problems do not complain because 'there is nothing they can do

about the problems anyway', PFDs are not life threatening, etc... However, quality of life issues and increasing cost of healthcare should be motivating people to pay more attention to PFDs. Women generally receive their first information about the pelvic floor prepartum and postpartum. After that time, the pelvic floor becomes hot news again when a woman has symptoms of PFD.

When women sought treatment for POP symptoms (with POP ≤ 2) their physicians often explained that surgery was not yet an option and gave reassurance that they did not have to worry and that no real treatment was indicated. This approach is misleading, because conservative treatment has earnt a prominent place in the series of treatment options for POP. Thus, the correct information has come too late. It is even more concerning that a study performed in 2003 demonstrated that PFMF assessment often remains a neglected part of outpatient gynaecological examination.[52]

DeLancey [53] called PFDs 'the hidden epidemic' and presented data on decreased quality of life in women. He also drew attention to the financial cost of health care. He ended his manuscript as followed: 'the challenges are before us and it is time to get to work'.

We wish to end this thesis on a similar note: it is time to embrace the challenges of the PFDs and attack the problems. Indeed, there is a lot to do.

As with all research, more questions have been raised than answers found. This may be the end of my PhD thesis, but our research will continue. We still want to know:

What is the effect of PFM training, including its effect on IMC? Does PFM training have a positively effect on the results of incontinence surgery? Is PFM training so effective that women will not need POP surgery two or three times in their life? Or even better: Can we instruct the women at risk so successfully that the result is no POP surgery at all?

Similarly in the case of serious avulsions in the pelvic floor, what is the effect of PFM training? Does training of severe asymmetrical PFM have a positive effect on the symptoms of PFD, or does it exacerbate the symptoms?

It will be challenging to continue the PFD research, but we desperately need more information, so there is indeed still a lot to do.

References

1. Swithinbank LV, Donovan JL, Du Heaume JC, et al. Urinary symptoms and incontinence in women: relationships between occurrence, age, and perceived impact. Br J Gen Pract 1999 49:897-900.
2. Drutz, HP and Alarab M, Pelvic organ prolapse: demographics and future growth prospects. Int Urogynecol J (2006) 17: S6-S9
3. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501-6.
4. Delancey JO, Ashton-Miller JA. Pathophysiology of adult urinary incontinence. Gastroenterology 2004; 126 (1 suppl 1): S23-32
5. Rao SS. Pathophsyiology of adult fecal incontinence. Gastroenterology 2004 Jan; 126 (1 suppl 1): S14-22
6. Shaw C, Atwell C, Wood F, Bittain K, Wiliams K. A quality study of the assessment and treatment of incontinence in primary care. Fam Pract 2007 Oct; 24(5): 461-7, Epub 2007 Aug 1.
7. Schraffordt Koops SE, Bisseling TM, Heintz AP, Vervest HA. The effectiveness of tension free vaginal tape (TVT) and quality of life measured in women with previous urogynecologic surgery: analysis form The Netherlands TVT Database. Am J Obstet Gynaecol 2006 Aug, 195(2): 439-44. Epub 2006 April 25.
8. Brubaker L. Surgical treatment of UI in women. Gastroenterology, 2004 Jan; 126 1 suppl 1): S71-6
9. Bachoo P, Brazzelli M, Grant A. Surgery for faecal incontinence in adults. Cochrane Database Syst Review. 2000; (2): CD001757. Update 2007; (2):CD001757.
10. Weiss BD. Selecting medications for the treatment of urinary incontinence. Am Fam Physician 2005; Jan 15; 71(2):315-22.
11. Potter J, Wagg A. Management of bowel problems in older people: an update. Clin Med 2005 May-Jun; 5 (3): 289-95.
12. Hunskaar S, Burgio K, Clark A, et al. Epidemiology of urinary and faecal incontinence and pelvic organ prolapsed. In: Abrams P, Cardozo L, Khoury S, Wein A, International Continence Society, Sociéte International d'Urology, eds. Incontinence, third annual consultantion on incontinence, 2005, vol 1, Basics and evaluation. Plymouth, England: Health Publications Ltd; 2005:255-312.
13. Weber AM, Richter HE. Pelvic organ prolapse. Obstet Gynecol 2005Sep; 106(3):615-34.
14. Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment for urinary incontinence in women. A Cohrane systematic review. Eur J Phys Rehabil Med 2008 Mar; 44(1):47-63.
15. Soligo M, Salvatore S, Milani R, Lalia M, Malberti S, Digesu GA, Mariani S. Double incontinence in urogynecologic practice: a new insight. Am J Obstet Gynecol 2003 189(2):438-443.

16. Shafik A, Shafik I, El-Sibai O. Effect of rectal distension on vesical motor activity in humans: the identification of the recto-vesicourethral reflex. J Spinal Cord Med 2007;30(1):36-39.
17. Leroi AM, Michot F, Grise P, Denis P. Effect of sacral nerve stimulation in patients with fecal and urinary incontinence. Dis Colon Rectum 2001;44(6):779-789.
18. Blok BF. Central pathways controlling micturition and urinary incontinence. Urology, 2002 May; 59 (5 suppl 1): 13-7.
19. Khullar V, Damiano R, Toozs-Hobson P, Cardozo L. Prevalence of faecal incontinence among women with urinary incontinence. Br J Obstet Gynaecol 1998 105(11):1211-1213.
20. DeLancey JO, Kearney R, Chou Q, Speights S, Binno S. The appearance of levator ani muscle abnormalities in magnetic resonance images after vaginal delivery. Obstet Gynecol 2003 101(1):46-53.
21. Dietz HP, Gillespie AV, Phadke P. Avulsion of the pubovisceral muscle associated with large vaginal tear after normal vaginal delivery at term. Aust N Z J Obstet Gynaecol 2007 47(4):341-344.
22. Tan JS, Lukacz ES, Menefee SA, Powell CR, Nager CW. Predictive value of prolapse symptoms: a large database study. Int Urogynecol J Pelvic Floor Dysfunct 2005;16:203-9.
23. Maclennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. Bjog 2000;107:1460-70
24. Samuelsson, EC Victor FT, Tibblin G, Svardsudd, KF. Signs of genital prolapse in a Swedish population of women 20 to 59 years of age and possible related factors. Am J Obstet Gynecol 1999;180:299-305.
25. Eva UF, Gun W, Preben K. Prevalence of urinary and fecal incontinence and symptoms of genital prolapse in women. Acta Obstet Gynecol Scand 2003;82:280-6.
Reproductive factors, family history, occupation and risk of urogenital prolapse. Eur J Obstet Gynecol Reprod Biol. 1999;82:63-7.
26. MacLennan MT, Harris JK, Karikki B, Meyer S. Family history as a riks factor for pelvic organ prolapse. Int Urogynecol J Pelvic floor dysfunction 2008 Aug; 19(8):1063-9. Epub 2008 Mar 19.
27. Rortveit G, Daltveit AK, Hannestad YS, Hunskaar S, Norwegian EPINCONT Study. Urinary incontinence after vaginal delivery or cesarean section. N Engl J Med 2003;348:900-7.
28. Swift SE. The distribution of pelvic organ support in a population of female subjects seen for routine gynaecologic health care. Am.J.Obstet.Gynecol. 2000 August 183(2): 277-85
29. Nygaard I, Bradley C, Brandt D. Pelvic organ prolapse in older women: prevalence and risk factors. Obstet Gynecol 2004;104:489-97.
30. Bump, RC, Mattiasson, A, Bo, K, Brubaker, LP, Delancey, JO, Klarskov, P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10-7.

31. Digesu GA, Salvatore S, Chaliha C, Athanasiou S, Milani R, Khullar V. Int *Do overactive bladder symptoms improve after repair of anterior vaginal wall prolapse?* Urogynecol J Pelvic Floor Dysfunct. 2007 Dec;18(12):1439-43. Epub 2007 Apr 11.
32. Kershen RT, Appell RA, De novo urge syndrome and detrusor instability after anti-incontinence surgery: current concepts, evaluation and treatment. Curr Urol Rep, 2002 Oct; 3(5):345-53.
33. Shafik A. Re: Cough anal reflex: strict relationship between intravesical pressure and pelvic floor muscle electromyographic activity during cough. Urodynamic and electrophysiological study. J Urol 2005;174(4 Pt 1):1502-1503; author reply 1503.
34. Gustilo-Ashby AM, Paraiso MF, Jelovsek JE, Walters MD, Barber MD. Bowel symptoms 1 year after surgery for prolapse: further analysis of a randomized trial of rectocele repair. Am J Obstet Gynecol. 2007 Jul;197(1):76.e1-5.
35. Krissi H. Medina C, Stanton SL. Vaginal wind – a new pelvic symptom Int Urogynaecol J 2003 14:399-402.
36. Hay-Smith J, Morkved S, Fairbrother KA, Herbison GP. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. Cochrane Database Syst Rev. 2008 Oct 8;(4):CD007471.
37. Laycock, J. Incontinence. Pelvic floor re-education. Nursing (Lond) 1991;4:15-7.
38. Brink CA, Wells TJ, Sampselle CM, Taillie ER, Mayer R. A digital test for pelvic muscle strength in women with urinary incontinence. Nurs Res 1994;43:352-6.
39. Devreese, A, Staes, F, De Weerdt, W, Feys, H, Van Assche, A, Penninckx, F, et al. Clinical evaluation of pelvic floor muscle function in continent and incontinent women Neurourol Urodyn 2004;23:190-7.
40. Pool-Goudzwaard AL, van Dijke GH, van Gurp M, Mulder P, Snijders C, Stoeckart R. Contribution of pelvic floor muscles to stiffness of the pelvic ring. Clin Biomech (Bristol, Avon) 2004 19(6):564-571.
41. Hodges PW, Sapsford R, Pengel LH. Postural and respiratory functions of the pelvic floor muscles. Neurourol Urodyn 2007 26(Whitehead et al.):362-371.
42. Messelink B, Benson T, Berghmans B, et al. Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn 2005;24:374-80.
43. Hoyte L, Thomas J, Foster Rt, Shott S, Jakab M, Weidner Ac (2005) Racial differences in pelvic morphology among asymptomatic nulliparous women as seen on three-dimensional magnetic resonance images. Am J Obstet Gynecol 193:2035-40.
44. Bo K. Can pelvic floor muscle training prevent and treat pelvic organ prolapse? Acta Obstet Gynecol Scand 2006 85(3):263-268.
45. Hagen S, Stark D, Glazener C, Sinclair L, Ramsay I. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct 2009 20(1):45-51.
46. Deindl FM, Vodusek DB, Hesse U, Schussler B. Activity patterns of pubococcygeal muscles in nulliparous continent women, Br J Urol 1993;72-51.

47. Blok BF, van Maarseveen JT, Holstege G. Electrical stimulation of the sacral dorsal gray commissure evokes relaxation of the external urethral sphincter in the cat. Neurosci Lett 1998;249:68-70.
48. Vereecken RL. Derluyn J, Verduyn H. electromyography of the perineal striated muscles during cystometry. Urol Int 1975;30:92-98.
49. Swift SE, Woodman P, O'Boyle A, Kahn M, Valley M, Bland D, et al. Pelvic Organ Support Study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. Am J Obstet Gynecol 2005;192:795-806.
50. Risk factors for genital prolapse in non-hysterectomized women around menopause. Results from a large cross-sectional study in menopausal clinics in Italy. Progetto Menopausa Italia Study Group. Eur J Obstet Gynecol Reprod Biol 2000;93:135-40.
51. Swift SE. The distribution of pelvic organ support in a population of female subjects seen for routine gynecologic health care. Am J Obstet Gynecol 2000;183:277-85.
52. Davis K, Kumar D. Pelvic floor dysfunction: a conceptual framework for collaborative patient-centred care. J Adv Nurs 2003 43(6):555-568.
53. DeLancey JO. The hidden epidemic of pelvic floor dysfunction: achievable goals for improved prevention and treatment. Am J Obstet Gynecol 2005 192(5):1488-1495.

Chapter 13
Summary

General

The scope of this thesis is the epidemiologic aspects of pelvic floor function and dysfunction in a general female population aged 45-85 years in the Netherlands by the analysis of cross-sectional data that are derived from a study in Brielle. The results are important for daily clinical practice and contributes to prevention and countermeasures for pelvic floor dysfunction (PFD).

PFD is a common disease in women. Most important and well-known symptoms are incontinence and pelvic organ prolapse (POP), but also vaginal noise, obstructive bladder and bowel disorders and sexual disorders are important symptoms. The impact of PFD is substantial and multidimensional. Because so many women develop POP symptoms in their life and also due to the global aging, costs in health care on POP-surgery are increasing.

Chapter 1 and 2 describe the general introduction of the study with the study aims and the studydesign.

Chapter 3 gives an overview of the authors and their affiliations.

Chapter 4 presents an 11.4% prevalence of the feeling and/or seeing vaginal bulging as the most significant symptoms of pelvic organ prolapse (POP). In the analysis we tested for risk factors and the three most important risk factors were POP-symptoms during pregnancy, maternal history of prolapse and heavy physical work, of which heavy lifting is modifiable.

The population impact of these three risk factors on the prevalence of symptoms was assessed by the Population Attributable Risk (PAR) (46%), which is the proportion of symptomatic women in the study population that is attributable to the risk factors in the final multivariate analysis. Clinicians should focus on risk factors in counselling of (pregnant) women to inform women to be aware of further exposures for themselves and their daughters.

Chapter 5 describes the prevalence of clinical relevant POP in a general population, measured with the POPQ of 17.5%. Multivariable analysis showed significant association with parity ≥ 2 and a mother with POP. The Receiver Operating Characteristic Curve (ROC) showed the highest Area Under the curve (AUC) of .759 for 'beyond the hymen' and .723 for 'at or beyond the hymen'. A clinical relevant POP-prediction model was performed on 17 questions. A prognostic index (Slieker-POP-Score) for clinical relevant POP based on eight questions was created. By using the developed POP-prognostic index the prevalence of clinical relevant POP can be estimated in a general population.

Chapter 6 presents the association of POP symptoms with bladder and/or bowel symptoms, using the questionnaire, the POPQ stages and the anatomical locations of the POPQ. Association between POP-stage and vaginal bulging scored significant, but not with bladder/bowel-symptoms. Comparing anatomic locations of POP with all pelvic floor dysfunction symptoms demonstrated significant correlations with loss of flatus, feeling anal prolapse, manual evacuation of stool per vaginam/anus, vagina bulging, constipation, pain during faecal urge ($p \leq .005$). POP is therefore associated with obstructive bowel disorders and strategies should be developed to prevent obstructive bowel disorders.

Chapter 7 describes the prevalence rate of urinary, faecal and double incontinence and its effect on the quality of life. We demonstrated significant differences in body mass index, menopausal status and family history between the different incontinent defined groups versus the non-incontinent group ($p < .005$). 37.5% scored no incontinence. Furthermore mixed urinary incontinence and urge urinary incontinence are significantly related to incontinence of flatus, liquid and solid stool. Women suffering from UUI alone have a risk estimate of 4.3 (CI 2.4-7.9) for liquid stool loss (LSL) and vice versa, women suffering from AI (Flat + LSL + SSL) have a RE of 5.8 (CI 1.8-18.2) for UUI. The quality of life, which is scored with the EQ-5D showed dramatic decrease in all different incontinent groups compared to the continent group, with the lowest score on DIF (.7960 versus .8500 in the continent women). In the VAS score especially the DI scored low compared to the continent women.

Chapter 8 describes vaginal noise as specific symptom of pelvic floor dysfunction. Vaginal noise was prevalent in 12.8% of which only a little bother was reported in 72.1%. The univariate analysis revealed significant risk estimates, especially on parity, urge and stress urinary continence, vaginal bulging, manual evacuation of faeces, incontinence of flatus, solid stool and fluid stool, with the highest risk estimate on incontinence of solid stool (OR 3.81

95% CI 2.04-7.12). In the multivariate analysis, most of the variables stayed significant, with surprisingly risk estimates on parity and incontinence of solid stool of 4.51 (95% CI 1.69-12.09) and 4.55 (95% CI 2.22-9.32), respectively.

Chapter 9 discusses the face validity and reliability of the first digital pelvic floor assessment scheme, which was based on the new standardized terminology of the ICS. The new assessment scheme based on the terminology of the ICS showed satisfactory face validity and intra-observer reliability. It can therefore be considered suitable for use in clinical practice. More detailed redefinition of the described outcome measures is necessary to improve the inter-observer reliability.

Chapter 10 presents the prevalence of the pelvic floor muscle function in a general population. In addition strength and endurance were analysed versus all other functions of the pelvic floor musculature including the involuntary muscle contraction and relaxation. The most important finding was that women with strong PFM were less able to perform an effective voluntary muscle contraction to counter sudden increase of intra abdominal pressure. This means that with assessing the PFM it is not informative enough to test the muscles for strength and endurance.

Chapter 11 analyses the association between the function of the pelvic floor musculature and the pelvic organ prolapse showing significant differences in voluntary muscle contraction and involuntary muscle contraction of the pelvic floor musculature. Between stage 0 and stage 1 an effective involuntary contraction scored 75.2% and 38.3%. Also in the group of symptomatic women the high score of a lack of an involuntary contraction scored almost as high (51.9%). No significant differences could be demonstrated in strength and endurance in relation to the different POP stages. Women with strong pelvic floor musculature were less able to perform an effective involuntary muscle contraction compared to the women with weak strength.

Chapter 14
Samenvatting

Algemeen

Het hoofdonderwerp van dit proefschrift is de epidemiologische aspecten van de functie en dysfunctie van de bekkenbodem in een algemene vrouwelijke populatie in de leeftijd van 45 tot 85 jaar in Nederland. De data komen uit een cross-sectionele studie die in Brielle is uitgevoerd. De resultaten zijn relevant voor de dagelijkse praktijk en dragen bij aan preventie en behandeling van bekkenbodemfunctie-stoornissen (BBFS).

BBFS komen veel voor bij vrouwen. De belangrijkste en meest bekende symptomen zijn incontinentie en urogenitale prolaps (de verzakking), maar ook vaginale geluidsvorming, obstructieve mictie en defecatie en seksuele dysfuncties zijn belangrijke symptomen. De impact van BBFS op vrouwen is groot en gecompliceerd. Omdat heel veel vrouwen BBFS ontwikkelen in hun leven en dit door de vergrijzing van de wereldbevolking alleen maar verder zal toenemen, stijgen de kosten voor de gezondheidszorg wat betreft de behandeling van urogenitale prolapsoperaties.

In **hoofdstuk 1 en 2** wordt de algemene introductie van de studie met de onderzoeksvragen en het design van de studie beschreven.

In **hoofdstuk 3** wordt een overzicht van de auteurs gegeven.

In **hoofdstuk 4** wordt de prevalentie van 11.4% van het meest significante symptoom van een urgogenitale prolaps beschreven: het voelen en/of zien van een vaginale uitstulping ('balgevoel'). In de analyse is bovendien getest op risicofactoren. De drie belangrijkste risicofactoren waren het voelen en/of zien van een vaginale uitstulping tijdens de zwangerschap, een moeder met een urogenitale prolaps en het verrichten van zwaar lichamelijk werk, waarvan alleen de laatste risicofactor beïnvloedbaar is.

De impact van deze drie risicofactoren op de prevalentie van de beschreven prolapssymptomen is berekend met de Population Attributable Risk (PAR) (46%). Dit betekent dat van 100 vrouwen met prolapssymptomen, 46

verklaard kunnen worden op basis van deze drie risicofactoren in de multivariate analyse. Artsen zouden zich op deze risicofactoren moeten richten in de anamnese van zwangeren en vrouwen met prolaps klachten en hen informeren over de risico's die zij en hun mogelijke dochters lopen.

In **hoofdstuk 5** wordt de prevalentie van klinisch relevante urogenitale prolaps beschreven in een algemene vrouwelijke populatie van 17.5%. De multivariate analyse presenteert een significante associatie met pariteit ≥ 2 en een moeder met urogenitale prolaps. De 'Receiver Operating Characteristic curve (ROC) demonstreert de hoogste Area under the Curve (AUC) van 0.759 voor een urogenitale prolaps voorbij het hymen en 0.723 voor een urogenitale prolaps op het hymen. Een klinisch relevant model om urogenitale prolaps te voorspellen is gebaseerd op 17 vragen. De prognostische index (de Slieker-POP-Score) voor klinisch relevante urogenitale prolaps die is ontwikkeld bestaat uit acht vragen. Met behulp van deze prognostische index kan de prevalentie van klinisch relevante urogenitale prolaps in een algemene vrouwelijke populatie worden geschat zonder een inwendig onderzoek.

In **hoofdstuk 6** wordt de associatie van urogenitale prolapssymptomen met blaas- en darmdisfuncties weergegeven op basis van de vragenlijsten, de POPQ-metingen en de meer specifieke anatomische locaties van de POPQ. Bij de POPQ-stadia was alleen de relatie met het zien of voelen van een vaginale uitstulping significant, maar geen enkel blaas- of darmsymptoom scoorde significant. In de analyse van de anatomische locaties van de POPQ met de andere bekkenbodemdysfuncties waren de volgende symptomen significant aanwezig: flatus, gevoel van anale prolaps, digitale ondersteuning bij defaecatie via de vagina of anus, voelen of zien van vaginale uitstulping, obstipatie, pijn tijdens aandrang voor defaecatie ($p \leq .005$). Urogenitale prolaps is hierdoor geassocieerd met obstructieve defaecatieproblemen en daarom moeten maatregelen genomen worden om obstructieve defaecatieproblemen zoveel mogelijk te voorkomen.

In **hoofdstuk 7** worden de prevalentiecijfers gepresenteerd van urine, fecale en dubbele incontinentie en de relatie met de kwaliteit van leven. Tussen de onderzoeksgroepen (urine incontinentie, fecale incontinentie en dubbele incontinentie) zijn significante verschillen aangetoond in body mass index, menopausale status en een moeder met prolaps- of incontinentieklachten in vergelijking met de groep vrouwen die geen incontinentieklachten heeft ($p < .005$). 37.5% van de vrouwen scoorde geen incontinentie. Verder zijn gemengde incontinentie en urge urine incontinentie (UUI) significant gerelateerd aan incontinentie voor flatus, dunne en vaste ontlasting. Vrouwen

die lijden aan UUI alleen hebben een risk estimate van 4.3 (CI 2.4-7.9) voor dunne ontlasting en vice versa, vrouwen die lijden aan anale incontinentie (dunne en vaste ontlasting plus flatus) hebben een risk estimate van 5.8 (CI 1.8-18.2) voor UUI. De kwaliteit van leven die gescoord is met de EQ-5D laat een dramatische daling zien in alle incontinente studiegroepen in vergelijking met de continente groep met de laagste score bij de vrouwen die lijden aan dubbele incontinentie inclusief flatus (0.7960 versus 0.8500 in de continente Group vrouwen). Met de VAS-score was de groep met dubbele incontinentie ten opzichte van de continente vrouwen het laagste.

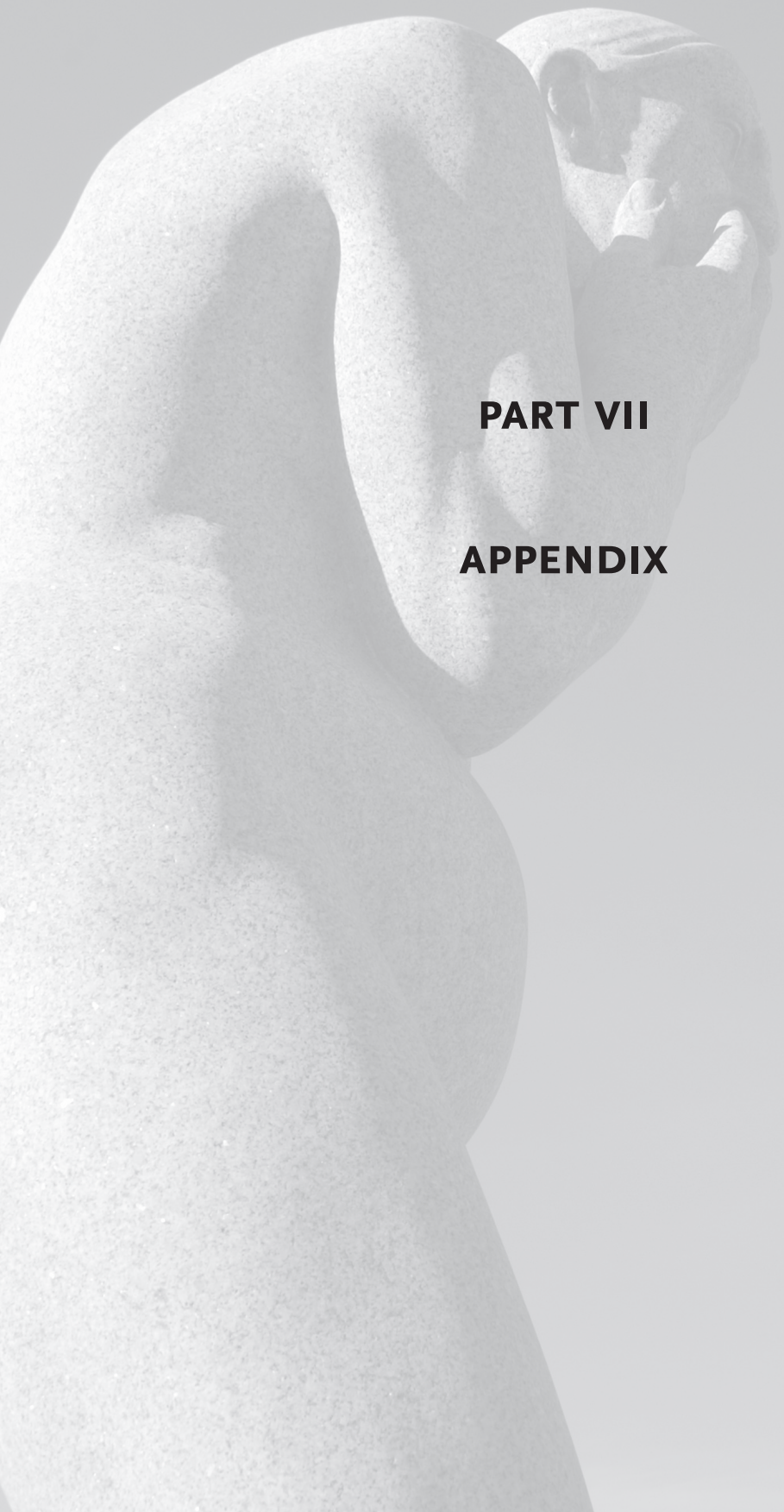
Hoofdstuk 8 beschrijft de prevalentie van vaginale geluidsvorming als apart symptoom van een bekkenbodemdisfunctie. Vaginale geluidsvorming was aanwezig in 12.8%. In deze groep had 72.1% hier slechts een beetje last van. De univariate analyse leverde significante risk estimates op, speciaal bij pariteit, UUI en stress urine incontinentie, vaginale uitstulping, flatus, incontinentie voor dunne en vaste ontlasting met de hoogste risk estimate voor pariteit en het verlies van vaste ontlasting (respectievelijk OR 3.81 95% CI 2.04-7.12 en 4.55 (95% CI 2.22-9.32).

In **hoofdstuk 9** wordt de face validiteit en betrouwbaarheid beschreven van het eerste digitale onderzoeksschema dat gebaseerd is op de nieuwe gestandaardiseerde terminologie van de International Continence Society om de bekkenbodemspierfunctie te testen. Dit nieuw functieonderzoek heeft een goede face validiteit en intra-beoordelaars betrouwbaarheid. Het kan daarom gezien worden als geschikt voor de dagelijkse praktijk. Voor de inter-beoordelaars betrouwbaarheid moeten eerst betere definities van de uitkomstmaten worden gedefinieerd om de inter-beoordelaars betrouwbaarheid te verbeteren.

In **hoofdstuk 10** worden de bekkenbodemspierfunctie beschreven in een algemene populatie. Bovendien worden kracht en uithouding geanalyseerd in relatie tot de andere spierfuncties inclusief de onbewuste aanspanning van de bekkenbodem musculatuur tijdens abdominale drukverhogingen. De belangrijkste bevinding is dat vrouwen met sterke bekkenbodemspieren minder goed in staat bleken om een effectieve onbewuste contractie te geven tijdens een verhoging van de intra abdominale druk. Dat betekent dat het testen van de kracht en uithouding van de bekkenbodemspieren niet voldoende is om voldoende zicht te krijgen op de functie van deze spieren.

Hoofdstuk 11 analyseert de associatie tussen de functie van de bekkenbodemspieren en urogenitale prolaps. Hierbij is een significant verschil aangetoond tussen de bewuste en onbewuste contracties van de bekkenbo-

demspieren. Met name tussen stadium 0 en stadium 1 scoorde een effectieve onbewuste contractie 75.2% en 38.3%. Ook in de groep vrouwen die symptomatisch was voor vaginale uitstulping was een lage score van effectieve onbewuste aanspanning aangetoond (51.9%). Er konden geen significante verschillen worden aangetoond wat betreft kracht en uithouding van de bekkenbodemspieren in relatie tot de verschillende urogenitale prolaps stadia. Vrouwen met sterke bekkenbodemspieren waren minder goed in staat tot een effectieve onbewuste contractie van de bekkenbodemspieren in vergelijking met de vrouwen met een matige spierkracht.



PART VII

APPENDIX

Publications

Symptomatic pelvic organ prolapse and possible risk factors in a general population. *Slieker-Ten Hove MC*, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. 2008b. Am J Obstet Gynecol. Feb;200(2):184.e1-7. Epub 2008 Dec 25.

Prediction model and prognostic index on pelvic organ prolapse in a general population. *Slieker-Ten Hove MC*, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. Int Urogynecol J pelvic Floor Dysfunct May 15.

Prevalence of pelvic organ prolapse symptoms and signs and their relationship to bladder and bowel disorders in a general female population. *Slieker-Ten Hove MC*, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME Int Urogynecol J Pelvic Floor Dysfunct. 2009 May 15.

Prevalence of double incontinence in a general female population. *Slieker-Ten Hove MC*, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME Accepted 2009 Neurourology & Urodynamics.

Vaginal noise: prevalence, bother and risk factors in a general female population. *Slieker-Ten Hove MC*, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME Accepted March 20, 2009 Int Urogynaecol Jour

Face validity and reliability of the first digital assessment scheme of pelvic floor muscle function conform the new standardized terminology of the International Continence Society. *Slieker-Ten Hove MC*, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. 2008a. Neurourol Urodyn. 28(4):295-300.

Pelvic floor muscle function in a general female population in relation with age and parity and the relation between voluntary and involuntary contractions of the pelvic floor musculature. *Slieker-Ten Hove MC*, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. 2009 Re-submitted April 21, Int Urogyn Journal.

Pelvic floor muscle function in relation to pelvic organ prolapse. *Slieker-Ten Hove MC,* Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. Re-submitted 2009 June, 4 Int Urogynaecol Jour.

Relation between low back pain and pelvicpain, pelvic floor activity and pelvic floor disorders. Pool-Goudzwaard AL, *Slieker-Ten Hove MC*, Vierhout ME, Mulder P, Pool J, Snijders C, Stoeckart R. *Int Urogynecol J Pelvic Floor Dysfunct*. 2005 Nov-Dec;16(6):468-74. Epub 2005 Apr 1.

Abstract-podium presentation, IUGA 2003.
Prevalence and bother of faecal symptoms in a community based white female population aged 45-85 year. Vierhout ME, Slieker-ten Hove MC, Sieradzan K, Schoenmaker T.

Abstract-poster ICS 2004.
Prevalence of bowel disorders and pelvic organ prolapse complaints in relation to urinary incontinence in a general female population. Slieker-ten Hove MC, Bloembergn H, Schoenmaker T, Vierhout ME.

Abstract-podiumpresentation, ICS 2004
Distribution of pelvic organ prolapsed in the general female population. Slieker-ten Hove MC, Chang W, Schoenmaker T, Vierhout ME (price of best clinical abstract).

Abstract-podium presentation ICS 2005.
Pelvic Floor muscle function in strictly asymptomatic parous women aged 45-85 years and its relation to pelvic organ prolapse. Slieker-ten Hove M C P, Pool-Goudzwaard A, Bloembergen H, Vierhout M.

Abstract-podiumpresentation ICS 2006
Sexual activity and satisfaction in relation to pelvic floor dysfunction and the influence on quality of life. Jong de M, Slieker-ten Hove M, Vierhout ME.

Abstract-poster, ICS 2007.
Digital assessment of the pelvic floor muscle function and dysfunction: the inter- and intra-observer reliability of the standardization of the International Continence Society. Slieker-ten Hove M C, Pool-Goudzwaard A, Eijkemans R, van Nierop P M, Dijkstra-Eshuis J, Burger C W, Vierhout M E.

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Curriculum vitae

Maria Cornelia Philippine (Marijke) werd geboren op 11 mei 1954 in Badhoevedorp, gemeente Haarlemmermeer. Na het behalen van de Middelbare Meisjes School (MMS) in Hilversum heeft zij de Opleiding Fysiotherapie gevolgd aan de SUPA in Utrecht en afgerond aan de Academie voor Fysiotherapie aan de Hogeschool Rotterdam. In 2002 studeerde zij cum laude af voor de Master of Arts in Health aan de Fontys Hogeschool te Eindhoven. Tijdens het afstudeeronderzoek onderzocht zij de logistieke processen in multidisciplinaire bekkenbodemcentra in Nederland en Nieuw Zeeland. Tijdens deze opleiding startte zij als coördinator/casemanager van het Bekkenbodemcentrum in het Erasmus MC. In deze periode is ook de voorbereiding en uitvoering van het promotieonderzoek gestart. In 2004 ontving zij de prijs voor 'best clinical abstract for podium presentation' voor de eerste rapportage van het onderzoek waarbij de relatie tussen de bekkenbodemspieren en de urogenitale prolapse werd gepresenteerd op het congres van de International Continence Society (ICS) en de International Uro Gynaecology Association (IUGA).

Vanaf 1994 is zij als opleider verantwoordelijk voor de organisatie van onderwijs in de bekkenfysiotherapie dat startte op de Hogeschool Brabant in Breda. Vanaf 2002 kreeg de driejarige opleiding bekkenfysiotherapie gestalte aan het Opleidingsinstituut van het Erasmus MC en werd uiteindelijk een Professional Master-opleiding Bekkenfysiotherapie die vanaf september 2007 is verplaatst naar de SOMT te Amersfoort. Daar is zij als afdelingshoofd verantwoordelijk voor de professional masteropleiding bekkenfysiotherapie.

Internationaal is zij betrokken bij de ontwikkeling en vormgeving van het vak bekkenfysiotherapie. Zij is zes jaar lid geweest van de Education Committee van het ICS en is momenteel lid van de Physiotherapy Committee, eveneens onder de vlag van het ICS. Verder geeft zij veel onderwijs in het buitenland in korte of langere cursussen over de bekkenfysiotherapie.

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