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Clinical and epidemiological aspects of pelvic floor dysfunction

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Front page:

Caspar Stromayr of Lindau recommended in 1559, that the use of sponge tightly rolled and bound with string, dipped in wax and covered with oil or butter be substituted for a pomegranate as a pessary[1].

Stromayr, C Die Handschrift des Schnitt – und Augenarztes Caspar Stromayr, Brunn, Berlin, 1925 (reprinted with permission from The Royal Library, Sweden)

Abstract

The overall objective of this thesis was to estimate the prevalence of symptomatic pelvic floor disorders, to study associations with putative risk factors and to evaluate surgical procedures for this condition.

Methods: Thirteen questions for identifying POP were constructed, and from these five questions were identified to in combination have a sensitivity of 92.5 % and a specificity of 94.5 % for POP. The final questionnaire was further tested and used in a cross-sectional study with 8000 randomly selected women, 30-79 years old, from the Swedish Population Register.

Two hundred and eighty-two of these women underwent a gynaecological examination of the pelvic floor anatomy. Specificity and sensitivity in the survey were 66.5 and 94.2 % respectively for the short questionnaire.

A case-control study was conducted with 454 women with self-reported symptomatic POP and 405 controls without symptoms randomly selected from the survey. All the women received a mailed questionnaire with 72 questions about factors suspected to be linked to risk, including obstetric history.

To investigate long-term results of surgery we invited women, who underwent surgery for stress urinary incontinence or pelvic organ prolapse in 1985-92 for a follow-up visit.

Results: Of 5489 women providing adequate information in the cross-sectional study, 454 (8.3%) were classified as having symptomatic POP. The prevalence rose with increasing age but leveled off after menopause. Parity seems to be more important than age as indicator of pelvic organ prolapse prevalence. The prevalence of frequent genuine stress incontinence (GSI) was 8.9 % and that of frequent urge incontinence 5.9%. Urinary incontinence frequently co-occurs with pelvic organ prolapse.

In the case-control study the response rate was 77 %. Indices of excessive stretching and tearing during labour (vaginal lacerations or/and episiotomies) were associated with increased risk of symptomatic POP. Instrumental delivery with forceps or vacuum did not seem to increase the risk of symptomatic POP, nor did length of delivery or maternal age at time for delivery. Abdominal delivery appeared to be protective for symptomatic POP.

Abdominal colposuspension is an effective method for treatment of GSI. The objective cure rate for correcting GSI was higher (93 %) than the subjective cure rate (54 %). Urge symptoms before operation were a negative prognostic factor for a good outcome in terms of subjective cure of incontinence, but had no impact on objective cure rate or satisfaction of the operation.

Subjective cure rate at follow-up visit for women operated on for POP, with curing of all symptoms of pelvic organ prolapse was 46%. Objective cure rate with satisfactory anatomical outcome was 56%. An unsatisfactory anatomical outcome was not necessarily associated with symptoms.

Conclusion: The prevalence of symptomatic POP was 8.3 %. The increase in prevalence with age halts after childbearing ages. Parity seems to be more important than age as an indicator of symptomatic POP prevalence. Excessive stretching and tearing during labour and multiple deliveries seem to be the main predisposing obstetric factors for symptomatic POP. Abdominal delivery emerged as a comparably protective strong factor. Objective outcome after surgery was higher than subjective outcome both for incontinence and prolapse surgery.

Keywords: Questionnaire, prevalence, risk factors, genuine stress incontinence, pelvic organ prolapse,

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To my mother Inga

ORIGINAL PAPERS

This thesis is based on the following papers, which will be referred to in the text by their Roman numerals:

I. **A short-form questionnaire for identification of genital organ prolapse.**
Tegerstedt G, Miedel A, Maehle-Schmidt M, Nyrén O, Hammarström M
Journal of Clinical Epidemiology, 2004, in press

II. **Prevalence of symptomatic pelvic organ prolapse in a Swedish population**
Tegerstedt G, Maehle-Schmidt M, Nyrén O, Hammarström M
Submitted

III. **Obstetric Risk Factors for Symptomatic Prolapse: A population-based approach.**
Tegerstedt G, Miedel A, Maehle-Schmidt M, Nyrén O, Hammarström M
Submitted

III. **Clinical outcome of abdominal urethropexy-colposuspension: A long-term follow-up**
Tegerstedt G, Sjöberg B, Hammarström M
Int Urogynecol Journal (2001)12:161-165

IV. **Operation for pelvic organ prolapse : a follow-up study**
Tegerstedt G, Hammarström M
Acta Obstetrica et Gynecologica Scandinavia;2004;83:758-763

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ABBREVIATIONS

B.C. ……	Before the birth of Christ
BMI ……	Body Mass Index
CI ……	Confidence Interval
GSI ……	Genuine Stress Incontinence
ICS ……	International Continence Society
IVS…….	Intra Vaginal Sling-plastic
LUTD ……	Lower Urinary Tract Dysfunction
OR ……	Odds Ratio
PFD…….	Pelvic Floor Dysfunction
PFM ……	Pelvic Floor Muscle Excercises
POP ……	Pelvic Organ Prolapse
POP-Q ……	Pelvic Organ Prolapse Quantification
RR ……	Relative Risk
TVT ……	Tension-free Vaginal Tape

INTRODUCTION

Female pelvic floor dysfunction in the form of urinary incontinence, pelvic organ prolapse and anal incontinence is common and affect quality of life but has low morbidity. The symptoms of female pelvic floor dysfunction often occur concomitantly[2-6].

Pelvic organ prolapse (POP) is known from early in history and surgical repair of prolapse is one of the oldest gynaecological surgical procedures[7]. It has been estimated that almost 40% of parous women lose pelvic floor support, which need not be symptomatic[8]. Firm data about risk factors, incidence and prevalence and natural history, as well as treatment results, are sparse and inconsistent concerning POP[8-16]. Valid prevalence information on symptomatic POP is important not only for the planning of gynaecological health care, but also for putting the clinical finding of POP in an individual patient into perspective.

It has been shown that the prevalence of urinary incontinence increases with age[17], and with an increasing number of elderly women in the population this will be an increasing social health problem. Every year approximately 6000 women will be operated on for POP and 4000 women for genuine stress incontinence (GSI) in Sweden. However, there are few long-term follow-up studies.

History

Pelvic Organ Prolapse

The ever first description of the condition POP can be found in an Egyptian medical text about 2000 before the birth of Christ (B.C.)[7]. A description of uterine prolapse can be found in the Ebers Papyrus from 1760-1550 B.C.[18]. In the writings of Susruta from India (900-300 B.C.) it was suggested that descended genitals should be lubricated with melted butter and then bathed with hot milk, following which the prolapse should be repositioned and a supporting bandage applied[18].

Hippocrates, the father of medicine (460-370 B.C.), attributed infertility problems to POP. He discussed the aetiology and proposed risk factors for POP such as wet feet, excessive

exertion, fatigue and sexual excesses, and as treatment for prolapse he suggested the use of succession. The woman was tied to a ladder which was inverted for 3-5 minutes in the hope that the prolapsed organ would return to its normal position[7](Figure 1).

Figure 1. Hippocratic succession (from Appolonius of Kitium *Illustrierter Kommentar zu der hippokratischen Schrift)* (*With permission from Royal Library, National Library of Sweden*)[19]

Uterine prolapse was one of the female diseases described by Cleopatra (300 B.C.), who recommended for therapy an astringent solution to be applied vaginally. Diocles of Carystos (350 B.C.) suggested for treatment a half pomegranate, dipped in vinegar and then inserted into the vagina[7]. Pomegranates were subsequently used for many years as mechanical devices.

Soranus (100 B.C.) advised against the Hippocratic succession which he thought was unbearable for the women and not evidence-based as well as against previously recommended treatment with beef inserted in the vagina, since this caused a putrid smell[20]. He discussed the aetiology and suggested accidents, delivery trauma and heavy lifting as risk factors for prolapse and also suggested that mental suffering and increasing age could be the cause. He recommended another therapy as follows: the patient should be given bed rest with reduced fluid and food intake for three days. The bladder and the rectum should be emptied with a

catheter or an enema. An alternative was sitz baths in warm wine and numerous drugs. If the uterus became gangrenous a surgical procedure was suggested.

In the late seventeenth century literature was published on the aetiology of uterine and vaginal prolapse as well as numerous medical and pharmaceutical conceptions and conservative methods in an attempt to keep the prolapsed organs within the lower abdomen[7]. But it was not until the eighteenth century that differentiation between a uterine prolapse and an inversion of the uterus after delivery was attempted. The difference between a prolapsed uterus and relaxation of the vaginal walls was first described in the middle of eighteenth century.

Figure 2. Testing of pessary **.**Johan von Horn 1696 "Den Wälöfwade Jordgumman"(*reprinted with permission from Hagström Library, Karolinska Institute)*

Thus, from the days of Hippocrates until the eighteenth century, only conservative treatment was available for prolapse, as different mechanical devices, made of sponge, cotton, linen, wood, bone ivory, cork or various metals (Figure 2-3). Vaginal packing, tampons, massages and exercise were also used with probably low degrees of success[7].

The first vaginal hysterectomy was performed in 1521[7]. The technique was to place twine around the prolapsed uterus, which was tightened until the organ was severed. The stump was treated with a mixture of wine, honey and aloes.

Figure 3. Pessaries used by Deventer 1701 (*with permission from Hagström Library, Karolinska Institute)* [21]

In the nineteenth century the development of surgical techniques and of anaesthesia led to several operative procedures for corrections of POP[7], such as cauterizing the prolapsed genitals and then obliterating the vagina[18]. This technique is very similar to the prolapse operation ad modum Neugebauer-Le Fort (1867), which is still in use. Surgical procedures for prolapse continued, however, to be handicapped by hazy knowledge and incomplete understanding of the uterine and vaginal supports[22]. The greatest importance was attached to the constriction of the vaginal mucosa, while little or no attention was given to the deeper structures, muscle and connective tissue[18]. The cardinal ligaments were identified in 1872[23] and fully described in 1895[24] including their significance for uterine support, and understanding of vaginal anatomy and supports of the pelvic fascia led to more successful techniques for surgical therapy.

In 1888 Archibald Donald, of Manchester, began to combine anterior and posterior colporrhaphy with amputation of the cervix as one operative procedure, and he also realized the importance of the deeper structures, muscles and connective tissue[25]. The operation was later somewhat modified by Forthergill, an associate of Donald[26], and subsequently came to be known as the Manchester operation. During the last hundred years the technique of the

Manchester operation, with modifications, has been spread over the world and is still the most commonly used surgical procedure for pelvic organ prolapse.

The first vaginal hysterectomy for prolapse was performed in New Orleans (Choppin ,1861). Choppin later presented the patient to a medical class with the uterus in her hand to prove that she had survived[7].

Figure 4. Anatomical description of uterine prolapse by Westermark, 1892 (*with permission from Hagström Library, Karolinska Institute).*

In the Scandinavian countries one of the first descriptions of surgical procedures for POP was published in 1892[27]. The operation was called colporrhaphia lateralis. A follow-up study on 144 women operated on for prolapse was presented at a Scandinavian meeting in 1913 (Hjalmar Forssner)[28]. Out of 122 women who came for an examination, 101 (87%) were cured and symptom-less.

In a study from 1921 a long term follow-up was published[29]. Postal questionnaires were sent to 750 women four year after the surgical procedure. The first question was "Does the womb keep up?" Five hundred and twenty-one women responded and the success rate was 87 % (455/521). Of 55 women with an unfavourable result, 29 were examined and 10 women had no prolapse.

Another follow-up study was published in1947 including women, operated on with the Manchester procedure[30]. The women answered a postal questionnaire three years after surgery. The most common preoperative symptom mentioned was the sensation of "something coming down", and a good result meant freedom from symptoms for the patient. A cured patient was counted as a case in which the patient had filled in the questionnaire to say that she was completely free from symptoms of "bearing down". Of the 549 total responders only 20 reported an unsatisfactory result, and 17 patients complained of incontinence of urine on straining, and of these three were not cured.

In a large American series of women operated on for POP, 1936-55, 960 cases was reported[31]. The preoperative symptomatology of all patients was carefully evaluated from the clinical record. Symptoms such as lower abdominal pain and constipation were infrequently recorded. A few patients had urinary symptoms such as frequency and burning or urinary retention. Interestingly it was reported that patients with a large prolapse have very few symptoms, while those with minimal relaxation may have a long list of complaints. The most common symptom was the presence of a bulging mass at the introitus or the sensation of something falling out, which was present in 82% of cases. No follow-up was done in this study.

In 1957, a review of 600 Swedish women operated on by the Manchester procedure was presented[18]. The description of the symptomatology preoperatively is similar to the American study. In addition, a follow-up of 466 surgically treated women was presented. The women responded to a questionnaire and 330 women were examined. The observation period was at least 4 years. The result was deemed to be successful if the women had been asymptomatic and without recurrence of the prolapse, and 66.5% of the women so were.

Eugene Pearce from Missouri-Kansas concluded in January 2004[32] :

> "*From a modern viewpoint, there are many criticisms that arise from the reports of the Manchester procedure. None of the articles identify site-specific support failures, and*

none of them report symptoms related due to genital prolapse or to site-specific lesions. Stress incontinence although mentioned in one paper, is not considered as a separate problem. In all the series reported, results were based on postal questionnaire. The Manchester surgeons deserve our respect. They analyzed genital prolapse and its surgical correction from an anatomic and functional view. They recognized the important role of the cardinal ligaments in the support of the uterus and upper vagina. They also recognized the critical element of restoration of vaginal anatomy."

Urinary incontinence

Urinary incontinence is seldom described as a symptom in older literature, probably due to the circumstance that, owing to social or hygienic factors in the community in general, it did not handicap women in daily life as much as a prolapse which could produce apparent physical symptoms. In 1864, Baker Brown published an article in the Lancet, which is probably the earliest documented surgical procedure for the treatment of urinary incontinence. A puncture was made under the arch of the pubis with a knife or trocar and an artificial channel entering the bladder was thus formed, into which a catheter was introduced. The patient wore an ingenious apparatus which served to keep the catheter in a good position and the urine under control[33].

In 1914 Kelly in the United States addressed the problem of stress urinary incontinence[33], and concluded:
"*There is a type of urinary incontinence in women, without manifest injury to the bladder and having no relation to fistula, which most frequently comes on following childbirth, but is occasionally seen in nullipara*".
He described a surgical procedure, which for the first time was reasonably effective for the treatment of stress urinary incontinence[34]. The technique was to reduce the area of the urethra and the anterior vaginal wall in the region of the vesical neck[33].

In 1937, Kennedy presented a modification of the Kelly plication[35], which with modifications is probably became the most commonly technique for the repair of cystocele and stress urinary incontinence. However, these vaginal operations for stress urinary incontinence were usually followed by an unacceptably high rate of recurrence[36]. An alternative procedure was the fascial, abdomino-vaginal sling technique for suburethral support, first described by

Stoeckels in1921[37]. In 1949, the Marshall-Marchetti-Krantz[38] abdominal operation was described, as a more effective surgical treatment for stress urinary incontinence. Four sutures were placed in the periurethral fascia on either side of the urethra and anchored at the symphysis periosteum. In 1961, John Burch[39] described the urethrovaginal fixation to Cooper´s ligament for the correction of stress incontinence, cystocele and prolapse. In an attempt to overcome some of the difficulties in the operation he inserted the finger of the left hand into the vagina, as the dissection in the space of Retzius was being made with the right hand[39]. That led him to use Cooper´s ligament for suture holding. During the last forty years the Burch procedure has been considered to be the "gold standard" for surgical treatment for stress urinary incontinence.

Two Swedish doctors have been important for research on the aetiology and treatment of stress urinary incontinence. In 1947, Axel Ingelman-Sundberg presented his extravaginal repair of the pelvic floor for prolapse of the bladder neck[40]. Two years later he presented 31 cases with women operated on with his plastic repair of the pelvic floor[41]. The bladder neck is repositioned by suturing the bladder pillars, which are then supported by a muscle plate. The latter is obtained by completely dividing both pubococcygeus muscles at the junction of the posterior and middle thirds, then suturing the anterior parts together in the midline. The procedure is called the IS-plastic and is not performed nowadays since it is known as a procedure which is not easy to learn. There are no long-term follow-up studies.

After previous research on pathophysiological objections during the1980s, Ulf Ulmsten, in co-operation with Papa Petros, in 1993 presented a new approach to genuine stress incontinence[42]. This theory was developed into a new surgical procedure, the intravaginal sling plastic (IVS), also known as the Tensionfree Vaginal Tape operation (TVT)[43], which during the last ten years has been spread over the world and together with the Burch procedure is the most commonly used surgical technique for stress urinary incontinence.

Anatomical aspects of pelvic floor support

In the late nineteenth century greater understanding of vaginal anatomy and supports of the pelvic fascia was obtained by human dissection. In 1839, the layer of dense tissue separating

the rectum from the bladder in men was described and given the name rectovesical septum. A few years later the layer between the vagina and rectum was described in women and given the name rectovaginal septum[44].

In 1866, in a histological study a muscular layer of the bladder and vagina separated by a layer of loose cellular tissue was demonstrated[45]. Today these two layers collectively are known as the *rectovaginal* and the *pubocervical* fascia. However, for many years there has been a discussion about the nature of vaginal tissue and the relationship of the vagina to the rectum and bladder. In a review 1997, it was concluded that there is no pubocervical fascia and that a more accurate description would be "adventitia"[45].

In 1909, the paravaginal support for the anteriolateral vaginal wall, by the connection to arcus tendineus fascia pelvis (white line) was described [46]. This approach to the paravaginal support was ignored for many years but was adopted again by Richardson in 1976[47]. He observed that loss of anterior wall descent occurred due to lateral detachment rather than midline stretching in women with stress urinary incontinence[48]

Victor Booney suggested as long ago as1934[49] that "*prolapse is a purely vaginal phenomenon, in the causation of which the uterus, does not play any direct part but acts more or less as a deterrent"*.

The bladder, vagina and rectum are all attached to the pelvic walls by a network of connective tissue fibre that is collectively called the *endopelvic fascia.* The vaginal wall consists of an inner epithelial lining surrounded by this endopelvic fascia. Together with the levator ani and the coccygeus muscles the endopelvic fascia, nerves and connective tissue (vessels, smooth muscle, elastin and collagen) form *the pelvic diaphragm* or *pelvic floor*. The cervix and the upper third of the vagina are supported by the uterosacral and cardinal ligaments. The bulbocavernosus, transverse perineal, and external anal sphincter muscles form the second layer of the pelvic floor, the *urogenital diaphragm*.

In 1992, DeLancey[50] presented a description of anatomical levels of support for each third of the vagina. An understanding of the anatomical supports to each third of the vagina may help us to understand functional outcome (Figure 5).

Level I.

The upper third of the vagina suspends the apex to the pelvic walls by the cardinal and uterosacral ligament, which insert into the supravaginal cervix and vagina. A defect at this level may result in a prolapse of the vaginal apex (uterine prolapse or vault prolapse).

Level II.

The middle third of the vagina is supported to the pubocervical fascia anteriorly and the rectovaginal fascia posteriorly. Lateral support is by attachment of the paravaginal fascia to the white line (arcus tendineus fascia pelvis). Defects may result in lateral/central cystocele or rectocele.

Level III.

The lower third of the vagina is supported directly at attachment to surrounding structures: perineal membrane, perneal body and m.levator ani. Defects here may result in uretrocele (urethral hypermobility) or deficient perineal body (rectocele).

Delancey two years later described the support for the urethra with the hammock hypothesis[51]:

> "*The urethra lies on a supportive layer that is composed of the endopelvic fascia and the anterior vaginal wall. This layer gains structural stability through its lateral attachment to the arcus tendineus fascia pelvis and levator ani muscle. Pressure from above compresses the urethra against this hammock-like supportive layer, compressing its lumen closed. The stability of the suburethral layer depends on the intact connection of the vaginal wall and endopelvic fascia to the arcus tendineus fasciae pelvis and levator ani muscles*"

Magnetic resonance imaging (MRI) in both patients and cadavers has recently supplemented the descriptive anatomy of the pelvic floor suggested in the studies of De Lancey[52].

Figure 5. Description of anatomical levels of support for the vagina. (*Reprinted with permission from JOL DeLancey).*

Pathophysiological aspects of pelvic floor disorders

Thus, during the last century we have gained greater understanding of vaginal anatomy and supports of the pelvic organ. During the last thirty years several studies on the pathophysiology of pelvic floor disorders have been performed. In 1977, it was stated in an American textbook[53] that "individual variation in the muscular and connective tissue components of support structures are important for the genesis of pelvic floor disorders".

Damage to the pelvic support

Pregnancy and childbirth may promote pelvic floor disorders in several ways.It is well known from many studies that lacerations to the anal sphincter during childbirth are associated with anal incontinence later in life[54-57]. The association between urinary incontinence, POP and childbirth has been less well studied.

Vaginal childbirth can contribute to POP, urinary and anal incontinence by direct damage to the endopelvic fascial support and by indirect and direct damage to the muscles and nerves of the pelvic floor[58]. It is shown that vaginal delivery may cause partial denervation of the pelvic floor [59]. It has also been shown by electromyography, pudendal nerve conduction tests and muscle histochemistry that women with pelvic floor dysfunctions have signs of partial denervation of the muscles[59-61]. It has been suggested that abnormalities in the levator ani muscle are present on MRI after a vaginal delivery but are not found in nulliparas[62].

The location of specific defects in the pubocervical fascia associated with anterior vaginal wall prolapse have been described[47]. The lateral paravaginal defect is the result of separations of the pubocervical fascia of the anterolateral vaginal wall from the arcus tendineus fascia pelvis (white line). A central vertical defect in the pubocervical fascia results from damage to the middle of the fascia.

Various locations for isolated tears in the rectovaginal septum has been observed in patients with a rectocele[44]. The most common one is a transverse separation immediately above its attachment to the perineal body. This tear results in a low rectocele, that is, the bulge begins in an area just inside the introitus. Almost equally common is a midline vertical defect, which probably indicates a poorly repaired episiotomy or poorly healed obstetric injury. This break

will result in a mid-line rectocele, and may involve only the lower vagina or extend almost all the way up to the vaginal apex (Figure 6).

Defects in the posterior vaginal wall may also correspond to the level of support[63]. High rectoceles are often associated with loss of uterine support and genital descensus, middle rectoceles are associated with separation of the rectovaginal septum and low rectoceles are associated with disruption of the perineal body[64].

Figure 6. Diagramatic representation of the various locations where breaks in the rectovaginal septum have been observed in patients with rectocele, seen through a posterior colporrhaphy incision (*Richardson, reprinted with permission from LWW*)[44]

Collagen and hormones

Several studies have reported a reduction in collagen contents in women with urinary incontinence and POP[65-68]. Collagen and elastin are believed to be important components in the connective tissue, explained as being the cement of the body, and provides some of the flexibility of tissues[69] .

Studies has shown that the oestrogen and progesterone receptor is situated in pelvic floor muscles and ligaments[70 71] and decreasing levels of oestrogen after menopause may cause decreasing elasticity in the tissues, and thus result in pelvic floor dysfunction[72]. Oestrogen receptors have been identified on skin fibroblasts[73] and there is a positive correlation between skin collagen and parameters of the urethral pressure profile[74]. Since the postmenopausal decline in skin collagen can be reversed by oestrogen therapy it may also improve urethral function by a similar process[75 76]. It has been suggested that serum relaxin mediates changes in connective tissue during pregnancy[77] and may explain why the incidence of urinary incontinence has been shown to increase during preganancy[78 79]. It is also reported that many women notice a deterioration in their ability to maintain continence just prior to menstruation, maybe as a effect of increasing levels of progesterone[80].

Pressure

The pressure of the pregnant uterus and the mother's higher weight may affect the pelvic floor in a negative way. Increases in intra-abdominal pressure, for example over-weight, may result in POP and stress urinary incontinence[58 81]. Constipation appears to be a factor in the pathogenesis of posterior vaginal wall defect[82]. Chronic constipation with coexistent chronic straining at stool has been associated with damage to the innervation of the pelvic muscles[83].

Weber *et al* comments as follows[84]:

"Does a rectocele develop as a result of abnormal bowel function, for example as a consequence of prolonged straining associated with constipation or paradoxic puborectalis contraction? Or does tissue damage during childbirth result in a weakness or defect in the posterior vagina that leads to trapping of stool and difficulty in evacuating the rectum? Althougt the answer is yet unknown, it is likely that combination of these 2 factors and others,

such as connective tissue strength, assumes greater or lesser degrees of causation in each individual."

In 1990 the integral theory of female urinary incontinence was presented[85]. This theory states that symptoms of urinary incontinence derive from laxity in the suburethral vagina or its supporting ligaments.

Classification and definitions

The International Continence Society (ICS) was founded in 1971, with over 60 participants from several countries attending the meeting. The primary interest of the ICS is to study urinary storage and voiding function of the lower urinary tract, diagnosis and management of lower urinary tract dysfunction (LUTD), and to encourage research into pathophysiology, diagnostic techniques and treatment.

In the third meeting in 1973, the Committee on Standardization of Terminology was established. Urinary incontinence was defined according to ICS as follows[86]:
"Urinary incontinence is involuntary loss of urine which is objectively demonstrable and a social or hygienic problem."

In a report from the Standardization Sub-committee of the ICS[87] it is a restated principle that symptoms, signs and condition are separate categories.
- ***Symptoms*** are the subjective indicator of a disease or change in condition as perceived by the patient, career or partner and may lead him/her to seek help from health care professionals. Symptoms may either be volunteered or described during patient interview. They are usually qualitative.
- ***Signs*** are observed by the physician including simple means to verify symptoms and quantify them. A classical sign is the observation of leakage on coughing. Observations from frequency volume charts, pad tests and validated symptom and quality of life questionnaire are examples of other instruments that can be used to verify and quantify symptoms.
- ***Condition*****s** are defined by the presence of urodynamic observations associated with characteristic symptoms or signs.

The symptom of urinary incontinence indicates the woman's statement of involuntary urine loss and can be defined as the two most common:

Urge incontinence – the complaint of involuntary leakage accompanied by or immediately preceded by urgency.

Stress urinary incontinence – the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.

Since the middle of the1990s the focus has been put on the need for international standardization of terminology for the description of POP. Research in this field has been hampered by lack of accepted definitions. Older classification such as Baden and Walker[88] and Beecham[89] were never validated (Figure 7).

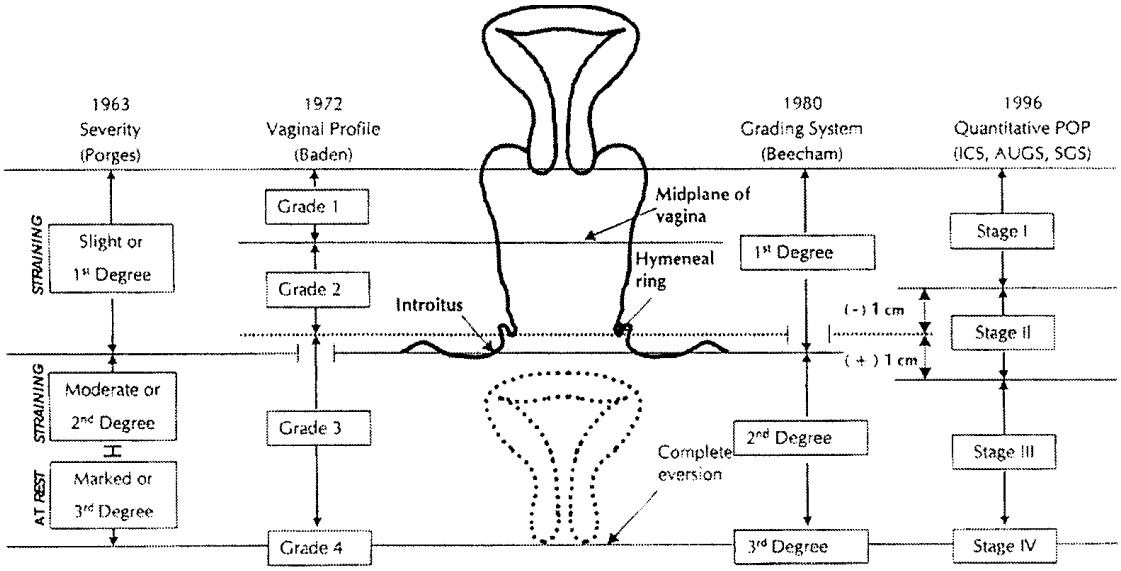


Figure 7. Comparison of ordinal classifications of pelvic organ prolapse 1963-1998 (*Reprinted with permission from Elsevier*[90])

In 1996, a report presented a standard system of terminology for the description of POP recently approved by the International Continence Society, the American Urogynecologic Society, and the Society of Gynaecologic Surgeons. The system is called the pelvic organ prolapse quantification system, POPQ[91]. This system has been accepted as a reliable method of describing pelvic support and comparing investigations over time[92 93]. The advantages with this system are the possibility of describing in detail variations in vaginal support. Site-

specific terms such as anterior and posterior vaginal wall are recommended as replacements for older terms such as cystocele and rectocele, since these terms may imply an unrealistic certainty as to the structures on the other side of the vaginal bulge.

However, the POPQ has been criticized as it can be difficult to learn and is perhaps not useful in the daily work, but researchers are advised to use this system[94]. The POPQ system defines POP as the descent of one or more of: the anterior vaginal wall, the posterior vaginal wall and the apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy. Absence of prolapse is defined as stage 0; prolapse can be staged from stage I to stage IV.

Physical examination with description of the pelvic floor anatomy with POPQ is as follows. The system uses six defined points around the vagina (two anterior, two posterior, and two apical) using the hymen as the fixed point of reference for these (Figure 8). Points above or proximal to the hymen are negative numbers, points below or distal to the hymen are positive, and the hymen is designated as zero (Figure 9). Stages in the POPQ are assigned to the most severe portion of the prolapse when the full extent of the protrusion has been demonstrated.

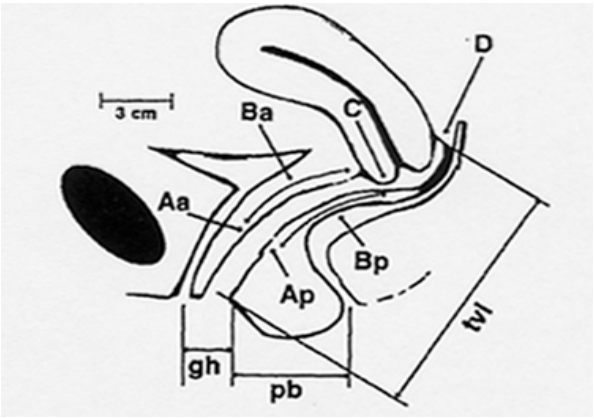


Figure 8. Six sites (points Aa, Ba, C, Bp and Ap), genital hiatus (gh),perineal body (pb) and total length (tvl) used for pelvic organ support quantification (*with permission from R.Bump*)

Staging of the prolapse with POPQ

Stage 0: No prolapse is demonstrated.

Stage I: The most distal portion of the prolapse is > 1cm above the level of the hymen.

Stage II: The most distal portion of the prolapse is ≤ 1 cm proximal or distal to the plane of the hymen.

Stage III: The most distal portion of the prolapse is > 1 cm below the plane of the hymen but protrudes no further than 2 cm less than the total length in centimetres.

Stage IV: Complete eversion. The distal portion of the prolapse protrudes to at least TVL-2 cm (total vaginal length).

Figure 9. A. Complete eversion of vagina. **B.** Normal support (*reprinted with permission from R.Bump)*

Symptoms of POP

In the ICS rapport from 1996[91] it was stated that functional deficits caused by POP and pelvic floor dysfunction are not well characterized or absolutely established. There is a need to develop, standardize, and validate various clinometric scales such as a condition-specific quality-of-life questionnaire for each of the four functional symptom groups thought to be related to POP.

The description of functional symptoms should be directed toward four primary areas[91]:

1. *Urinary symptoms*
2. *Bowel symptoms*
3. *Sexual symptoms*
4. *Local symptoms*

Urinary symptoms

Women with POP often have urinary symptoms such as stress and/or urge incontinence and also voiding dysfunction. Anterior wall prolapse can descend and obstruct the urethra[95 96], and with higher stage of prolapse the symptoms of stress incontinence may improve. Reduction of the prolapse with a pessary can render stress incontinence and this phenomenon has been termed *occult* or *potential* stress incontinence[90] and is also used to describe stress incontinence that develops following correction of the POP amongst women who were continent prior to surgery. However, it is uncertain if the preoperative barrier test really is effective to identify women with proplapse who also should need an anti-incontinence procedure[97].

Women with POP often have storage symptoms such as increased frequency and nocturia[98] as well as voiding symptoms such as slow stream, hesitancy and feeling of incomplete emptying[98 99]. It is not certain that these symptoms recede after surgery. When residual volume was present and could be reduced preoperatively by a pessary, this was the best predictor of normalization of residual urine post operatively[100].

Bowel symptoms

Women with POP often report bowel dysfunction as difficulty with defecation or faecal incontinence[6 84], but these symptom are not associated with the stage of posterior vaginal wall

prolapse[84]. Posterior vaginal wall prolapse can frequently be seen on examination and in radiological studies, but these findings have not been shown to correlate with patient symptoms[84 101] and size of the rectocele does not correlate with the symptoms[101]. It was assumed that only perineal descent ≥2cm was significantly more likely in the women with bowel symptoms and prolapse[102].

Many bowel symptoms have been postulated as being due to posterior vaginal wall prolapse while data have not established this relationship[102]. Constipation is often reported as a symptom of POP. However, constipation might induce POP. It is possible that women with a symptomatic posterior vaginal wall prolapse and constipation, after surgery may relieve symptoms related to stool trapping, but due to chronic constipation and straining have a higher risk of recurrence of POP[84 103].

It is also reported that the prevalence of faecal incontinence may be as high as 17 % in women with urinary incontinence[6] compared with 2-3% in the general population[104]. Faecal incontinence should not be considered as a symptom of posterior vaginal wall prolapse but is most often caused by an incompetent anal sphincter mechanism, and any women with this complaint need further evaluation of the anal sphincter and neurological function[105 57 59].

Sexual symptoms

Firm data on how POP and urinary incontinence affects sexual function in women are sparse and inconsistent, and also limited by the selection of women for the studies. Most of the studies are based on women admitted to hospital for surgery of POP, thus making inferences on the general population difficult. It has been shown that women with prolapse and urinary incontinence do not differ from women without these symptoms in studies on sexual function[106 107]. The presence or grade of prolapse was not associated with dyspareunia or vaginal dryness. Vaginal anatomy seems thus not to correlate with sexual function. Most women who complain of vaginal dryness or tightness had large introital diameters[107].

Women with prolapse seems, however to be more likely than women with urinary incontinence to be sexually inactive[108]. Of the patients with POP, stage III or IV, who were sexually active, more than a third, felt that their prolapse affected their ability to have sexual

relations, which is in line with a study noting a mild to moderate correlation between the impairment of sexual activity and more severe prolapse in all three compartments[109].

The perception of sexual satisfaction is multifactorial, complex and difficult to study, and there is a need for further research. The woman's emotional well-being, partner relationship, physical health and quality of life all influence satisfactory sexual function. With knowledge, that posterior colporrhaphy may result in dyspareunia, care should be taken about indications for surgery.

Local symptoms

The most common symptom of POP is the sensation of "something coming down"[30], a symptom that has been described for at least four thousand years[7]. Since POP is often asymptomatic until the descending segment is through the hymen, POP may not be recognized by the woman until advanced anatomical changes exist[11 110]. It is assumed that symptoms, especially local symptoms, increase with increasing POPQ stage[11 109 110]. However, symptoms have little relation to specific compartment or POPQ-value but a sensation of something coming down and visualization of a "bulge or vaginal protrusion" is the symptom most closely associated with POP[110].

Vaginal pressure or heaviness, vaginal pain, sensation of tissue protrusion, low back pain and observation of a mass are all local symptoms suggested in the ICS report from 1996 [91]. Low back pain seems to be a non-specific symptom, and was noted in a study linearly inversely associated with descent of prolapse: however, patients with greater descent of the leading edge of their prolapse reported less low back pain[111].

Vaginal heaviness has an uncertain relationship with anatomical prolapse. A sense of heaviness was reported by 9.7% in the prolapse group and by 7.5% in the group with no prolapse in a Swedish study[8], in line with another Swedish study[112] where 15% of the women reported pelvic heaviness (17% among women 40 year-old women and 12% among 60-year-old women). Symptoms of heaviness do not necessarily imply POP.

Surgical treatment of stress urinary incontinence

Many different surgical procedures have been described for the treatment of stress urinary incontinence. A common feature of the surgical procedure is the effort generally to lift and support the urethra-vesical junction and the surgical procedures can be placed in seven categories:

1. Anterior vaginal repair (Kelly, Ingelman-Sundberg)
2. Open abdominal retropubic suspension (Marshall-Marcetti-Krantz, Burch colposuspension)
3. Bladder-neck needle suspensions (Stamey)
4. Laparascopic colposuspension
5. Suburethral sling procedures (tension-free vaginal tape, TVT)
6. Periurethral injections (collagen)
7. Artificial sphincters

The literature on the effectiveness of surgical treatment has been sparse and limited. Many reports include case series with small numbers of patients and follow-up time is often short[113]. Evaluation of symptoms pre-and postoperatively is not standardized and subjective outcome is seldom reported. It was concluded in a review report (1996) that until high-quality studies have been presented the best clinical practice cannot be based on scientific evidence[114]. The choice of procedures may be influenced by surgeon's preference and local hospital traditions.

Open abdominal retropubic suspension seems to be better than anterior vaginal repair with regards to cure rates (83 % dry at one to five years after operation versus 63 %)[115]. In a Cochrane report (2004) it was concluded that bladder neck needle suspension surgery is probably not as successful as open abdominal retropubic suspension. There was not enough information to comment on comparisons with suburethral sling operations[116]. In a prospective long-term Nordic multicentre study[117], 72 of 85 patients were objectively and subjectively cured after the TVT operation.

Randomized trials are the gold standard for comparing the effectiveness of different treatments, and recently some randomized studies have been reported. A British study presented a well designed randomized study comparing TVT and open colposuspension[118]. The trial was conducted in 14 centres in the United Kingdom and Ireland, and 344 women were included. The outcome was assessed by a quality-of-life questionnaire, validated questions about symptoms, clinical examination and a pad-test. After two years, 63% of the

TVT group and 51% of the colposuspension group were objectively cured. The TVT group returned to normal activity and work earlier, than the colposuspension group.

Laparoscopic colposuspension appears to have short-term benefits, such as faster recovery and shorter hospital stay compared with open colposuspension. The disadvantages are the technical difficulty with more complications and a long time in the operating theatre[119]. Few randomized trials are presented. A randomized Finish study, comparing laparoscopic mesh colposuspension and TVT, shows higher objective and subjective cure rates for TVT[120]. A Swedish randomized trial compared open colposuspension with laparascopic colposuspension using mesh and staples[121]. Open colposuspension had a higher objective and subjective cure rate one year after surgery, but with greater blood loss, greater risk of urine retention and a longer hospital stay than after laparoscopic colposuspension. In a Cochrane review from 2002 it is suggested that if a laparoscopic procedure is performed two paravaginal sutures appear to be more effective than one. Whether mesh is as effective as sutures and the place of laparascopic colposuspension in clinical practice are still unclear[122].

Data from randomized studies have shown that peri-urethral injection of established manufactured bulking agents (collagen) results in subjective and objective short-term improvement of symptomatic stress urinary incontinence. However, the lack of long-term follow up indicates that injection therapy cannot be recommended at present as an alternative therapy for women fit for other surgical procedures[123]. Finally, until more data have been presented artificial sphincters have a small place in the clinical practice and are recommended, by the ICS in cases in which previous attempts at surgical treatment have failed[124].

Surgical treatment of POP

There is a lack in knowledge about the correlation between POP and symptoms, and outcome after surgery in terms of subjective and objective cure rate has not been studied. There is evidence that surgery successfully can “cure” the vaginal bulge[18 30 103 125-128]. Outcome measures of surgery should also address quality-of-life issues including the relief of symptoms related to prolapse and the maintenance or restoration of visceral and sexual function. Surgery for POP has been empirical and most studies, published in the literature are observational and retrospective.

The surgical treatment has to preserve vaginal axis, vaginal length and vaginal function. This is of most importance for sexually active women and should be discussed with all women when an operation is considered. There are numerous of surgical procedures for the treatment of POP, but no single method is completely satisfactory. The recurrence rate remain high[129] with a re-operation frequency of 29%[14 129].

Anterior vaginal wall prolapse

It is suggested that the repair of the anterior wall is the most challenging part of pelvic surgery and the most common site for recurrence with failure rates of up to 20-40 % [45 130]. The most frequently reported procedure is the anterior colporrhaphy which includes dissection through the vaginal mucosa and plication of the pubocervical fascia in the midline. It is often combined with another reconstructive procedure, such as the Manchester operation. This technique is recommended for central defects, is easy to learn and has low surgical morbidity[45 131].

Procedures for paravaginal defect repair are technically more challenging and were first described in 1909[46]. The procedure is recommended for lateral defects and restores the lateral attachment of the pubocervical fascia to the pelvic sidewall of the white line (arcus tendineus fascia pelvis), and can be accomplished abdominally (open or laparoscopy)[132-134]. However, there are few long-term follow-up studies[135].

It has been reported that repair with synthetic material (polypropylene, polyglactin) may reduce the recurrence of anterior vaginal wall prolapse[136]. However, mesh erosion was identified in 25% of the patients as well as foreign-body complications, and is recommended only for recurrence prolapse[137]. In a prospective, randomized control study the outcome after anterior colporrhaphy with the use of three different techniques was compared[138]. Symptoms were assessed by questionnaire and analogue scales. Objectively cure was defined as satisfactory (stage I, POPQ) or optimal (stage 0). One hundred and fourteen women were randomly allocated to standard anterior colporrhaphy, standard with mesh (polyglactin) or to paravaginal repair. It was concluded that the three techniques provided similar anatomical cure rates and symptom resolution for anterior vaginal prolapse repair.

Posterior vaginal wall prolapse

Many surgical procedures have been reported. The traditional posterior colporrhaphy may correct the anatomical defect but is shown to increase the risk of dyspaurenia when the levator muscle is plicated, due to constriction of the vaginal tube[84 103 139].

The site-specific posterior colporrhaphy was presented after the new anatomic and pathophysiological theories was presented[44].The goal with this procedure is to identify and repair the fascial break without performing a levator plication. It has been shown that the site-specific repair may provide anatomical correction of rectoceles with alleviation of associated bowel symptoms[126-128]. The technique may also decrease the risk of dyspaurenia compared with traditional posterior colporrhaphy[140].

For patients with high rectoceles or/and recurrence of posterior vaginal wall prolapse, the use of mesh has been suggested as a mean to improve the strength of the repair[64]. It is hither to only recommended for recurrence of posterior vaginal wall prolapse and further studies are needed for all these procedures[64 105].

Apical prolapse (Uterine prolapse or vaginal vault prolapse)

The Manchester operation with amputation of the cervix and uterus suspension to the cardinal ligaments have for long time been the gold standard for the treatment of uterine prolapse, with a low rate of complications. Vaginal hysterectomy today is a popular method for repairing uterine prolapse, but vaginal hysterectomy alone is not effective in correcting uterovaginal prolapse and has to be combined with specific steps to suspend the apex[124]. However, it was shown that vaginal hysterectomy was associated with longer operative time and more blood loss compared to the Manchester operation [141].

Vaginal vault prolapse following hysterectomy probably represents a failure of support of the upper third of the vagina, the cardinal or uterosacral ligaments[142 143]. Posterior enteroceles (with uterus intact) result from a defect in the superior or transverse portion of the rectovaginal fascia[143]. Vault prolapse often exists together with anterior and posterior vaginal wall prolapse[50]. The surgical procedures for treatment of vaginal apex prolapse may be performed by the abdominal, vaginal or laparascopic routes and there has been a trend

towards site-specific defect repair based on anatomical dissections[47 50 144]. Abdominal sacrocolpopexy has been a successful procedure for treatment of vaginal vault prolapse[145 146-148]. Synthetic mesh materials are often used as a suspensory bridge between the vaginal cuff and the sacrum. However, there is risk for infection and vaginal erosion with the use of mesh.

Sacrospinosus ligament fixation is the most commonly used vaginal approach for the treatment of vaginal vault prolapse. This procedure can be unilateral or bilateral. The advantage with the vaginal procedure is decreased immediate operative morbidity. It was concluded in a retrospective study with 292 women who had undergone sacrospinosus fixation that this procedure is safe and effective with rare major complications[149]. One randomized study with 88 women had compared bilateral sacrospinosus fixation, combined with paravaginal repair and abdominal sacrocolpopexy[150]. It was concluded that the abdominal approach was more effective. Another randomized prospective study with 94 women concluded that sacral colpopexy and vaginal sacrospinosus colpopexy are both effective in the treatment of vaginal vault prolapse[151].

Other vaginal procedures have been described for the treatment of vaginal vault prolapse, such as bilateral attachment of the vaginal cuff to iliococcygeus fascia, which has been reported as an effective method with a low rate of recurrence[152]. Uterosacral ligament suspension with site-specific fascia repair has also shown a high success rate[153 154]. The patient groups in these studies are, however, small. In older women who are in poor health and not sexually active, the colpocleisis can be a safe alternative. This is an established technique and is effective in treating vaginal apical prolapse in selected situations[155]. There are few reports of laparoscopic access for the treatment of vaginal vault prolpase. The technique is difficult to learn due to the need for suturing and extensive dissection and the operative time will be long. The clinical outcomes appear to be consistent with those for the abdominal approach[156].

Thus, surgical procedures for many years have not been the subject to the same evaluation as medical therapies. The literature has been limited since it often consist case series including small numbers of patients and an unclear definition of the indications for surgery indication. Further study is needed with a standardized preoperative questionnaire for symptoms as well as POPQ examination in order to define anatomical defects. It is necessary to have a follow-up period of several years and assessment on effects on functional symptoms.

AIMS OF THE PRESENT STUDY

The overall objective of this thesis was to estimate the prevalence of symptomatic pelvic floor disorders, to study associations with putative risk factors and to evaluate surgical procedures for this condition. The specific aims were:

1. To estimate the association between functional symptoms and pelvic organ prolapse (Paper I)

2. To create and validate a questionnaire for identification of women with pelvic organ prolapse (Paper I)

3. To estimate the prevalence of symptomatic pelvic organ prolapse by age and parity in a Swedish urban female population (Paper II).

4. To assess the importance of obstetric factors as risk indicators for symptomatic pelvic organ prolapse in a retrospective case control study with prevalent cases (Paper III).

5. To investigate long-term results of surgery for genuine stress incontinence in terms of objective and subjective cure rates, postoperative complications and side effects (Paper IV).

6. To investigate long-term results of surgery for pelvic organ prolapse in terms of objective and subjective cure rates postoperative complications and side effects (Paper V).

MATERIAL AND METHODS

Subjects

Paper I

Phase I;

We studied 399 women in whom POP was either confirmed or excluded by gynecological examination. Two hundred had confirmed POP, and they either attended the outpatient clinic for symptoms or were on the waiting list for surgery. All 200 women were routinely examined by a gynaecologist at the Department of Obstetrics and Gynaecology, Stockholm Söder Hospital. The other 199 women were coming to the outpatient clinic for various gynaecological problems such as dysfunctional bleeding, menopausal symptoms or cervical dysplasia, but genital organ prolapse was excluded in these women by one of the gynaecologists (MH) in the research team. The pelvic floor anatomy was defined in conformity with standards recommended by the International Continence Society, the pelvic organ prolapse quantification system, POPQ[91].

Phase II;

The questionnaire was validated on 282 women participating in the screening survey.

Paper II

Eight thousand randomly selected female residents in Stockholm, aged 30-79 years, were mailed a questionnaire about symptoms of POP. In total, 5500 women (69%) returned more or less complete answers. Six hundred and ninety-seven women actively declined participation, 8 questionnaires were returned unopened due to erroneous address information.

The age information from the women was compared with the age information from SPAR, a continuously updated population register. Eleven of the women who answered the questionnaire were excluded because of inconsistencies in age information, leaving a total of 5489 women in the study population. The age of women in the study is quite similar to that of the women in the whole sample (Figure 10).

Paper III

Four hundred and fifty-four women with self-reported symptomatic POP, identified among 5489 women participating in the population survey (paper II), and 405 controls without symptoms randomly selected from the same survey. Sixty-four women actively declined participation. Of 454 cases 344 (76%) women returned an answer and of 405 controls 312 (77%) answered. There were a total of 554 women of out of 656 women, with at least one childbirth (322 cases and 212 controls), and the analyses of the obstetric risk factors in this study are based on these parous women**.**

Paper IV

Between 1985 and 1992, 169 women between 27 and 79 years old underwent abdominal urethropexy-colposuspension at Stockholm Söder Hospital. They were invited to participate in this long-term follow-up study, 5-11 years after the operation. One hundred and thirty-one women (78%) were willing to attend for a clinical re-examination; 38 were lost to follow-up. Of these 38, 15 had died, 6 had changed address and could not be traced and 17 did not reply or did not wish to come for an examination.

Paper V

During a 3-year period from 1986 to 1988, 269 women underwent surgery for POP at the Department of Obstetric and Gynaecology, Stockholm Söder Hospital. They were invited to a long-term follow-up visit, 10-12 years after operation. Sixty-seven (25%) women had died, 74 were lost to follow-up (8 had changed address and could not be traced, 17 did not reply, 5 had developed Alzheimer's disease and could not be evaluated, and 44 did not want to attend a follow-up visit), but 128 (47%) attended. The medical records were reviewed for women not attending follow-up (n=131). The records from 10 subjects could not be traced.

Study design

Epidemiological studies (Papers I-III)

In study I (Paper I) the aim was to construct a simple questionnaire that, with a minimum of questions, could accurately and reliability identify women with POP. The women included in phase 1 (training set) answered 13 questions perceived to be valuable for the diagnosis (***Appendix I***). In order to evaluate the sensitivity of these questions, alone or in various combinations, they were administrated to 200 women with confirmed genital organ prolapse,

either attending the outpatient clinic for symptoms or being on the waiting list for surgery. The specificity was evaluated in another 199 women. Only women with no demonstrable prolapse (stage 0) were accepted in this group. To assess reproducibility of the answers, 100 women from each group were given the same questions a second time one month later. When combining both groups of patients to estimate the importance of each question and its ability to add to the overall predictive ability, the resulting logistic regression model after stepwise elimination of redundant questions consisted of five questions together with age (final questionnaire) that was forced into the model. (Table II).

The final short questionnaire (***Appendix II)*** was then validated in a test set taken from a cross-sectional study with randomly selected women from the computerized and continuously updated Swedish Population Register (Papers I-III) for analysis of prevalence of symptomatic POP. The gold standard was gynecological examinations of the pelvic floor anatomy performed strictly according to the pelvic organ prolapse quantification system by two qualified gynecologists (GT, AM), blinded to the questionnaire responses. In the cross-sectional study of POP prevalence (Paper II), women with a questionnaire score exceeding the cutpoint established in study 1 were considered to have symptomatic POP. The numbers of such cases were divided by the total number of responding women in the respective population strata.

Finally a case-control study was conducted to identify obstetric factors associated with subsequent presence of symptomatic POP. The case subjects were defined as all women (n=454), whose scores were indicative of symptomatic genital organ prolapse, while the controls (n=405) constituted a random sample from the women whose answers indicated absence of genital organ prolapse.

Follow-up studies (Papers IV-V)

To investigate long-term results of surgery for genuine stress incontinence and POP we invited women for a retrospective follow-up study. The women had undergone surgery for stress urinary incontinence (Paper IV) or POP (Paper V). Pre- and postoperative data were abstracted from the records. At the follow-up visit, the medical history was obtained following a predefined protocol constructed for the studies with the emphasis on functional

symptoms of pelvic floor disorders. The women underwent a gynaecological examination (see below).

Questionnaires (*Papers I-III*)

For the construction of a questionnaire, perceived to be valuable for the diagnosis of POP we compiled 13 questions often used in medical history taking **(*Appendix I*).** The questions inquired about symptoms of stress or urge urinary incontinence, local symptoms of POP and bowel symptoms. The final questionnaire (Paper I-II) included five questions and was combined with questions about age, parity, previous operations for pelvic organ disorders and presence of genuine stress incontinence (***Appendix II)***

The questionnaire in paper III contained 72 questions about education, medical history, height and weight, life style factors, family history (mother or sister) of surgery for stress urinary incontinence or POP, eating habits, bowel movements, obstetric history and physical exercise.

Follow-up protocol *(Papers IV-V)*

The protocol at follow-up visit included questions about satisfaction and problems after operation and functional symptoms of pelvic floor disorders. The schedule also included questions about demographic data, past diseases, concurrent diseases; obstetric history, gynaecological diseases and operations, hormone replacement therapy, smoking and sexual function before and after surgery

Clinical examination

The pelvic floor anatomy was defined in conformity with standards recommended by the International Continence Society, the pelvic organ prolapse quantification system, POPQ[91] (Paper I). Before the performance of the examinations, the three gynaecologists in the research team, trained in the technique together. The examination was performed with the women in the dorsal lithotomy position. All the women were asked to empty their bladder before examination. With a speculum inserted into the vagina, the anterior, posterior vaginal wall and superior vagina (cervix/cuff and posterior fornix) was examined. The woman was asked to strain, and measurements at different vaginal segments as well as an overall stage of prolapse were made with a swab, marked in centimetres. We defined a prolapse as stage I-IV as recommended in an article from The National Institutes of Health 2001[94].

The pelvic floor anatomy at the follow-up visit in Paper V was defined in the same way, but in Paper IV we used older definitions such as cystocele, uterine prolapse, enterocele and rectocele for the description of prolapse at the follow-up visit, as the planning for this study was performed and started up in 1996, before POPQ system was presented.

In phase II (Paper I) the examinations were double blind, as neither the investigator nor the women knew whether if she was invited as a case or as a control, according to our definitions.

In Paper IV the residual volume was measured before the gynaecological examination. A provocation test was performed where the bladder was filled by a catheter up to a volume of 150 ml and the women were tested on coughing and vertical jumping in the standard position.

In Paper V we defined a recurrence of prolapse as stage II or more.

Dropout analysis

In the cross-sectional study (paper I-II) we sent reminders to non-responders after one and two months. Moreover, we tried to contact 100 randomly sampled non-responders after two reminders for a short telephone interview. In paper III we sent reminder after one month to non-responder. The medical records were reviewed for women not attending follow-up in paper V and pre-and postoperative data were abstracted.

Statistical methods

The statistical software used in all the studies was the NCSS system and in papers I-III the SAS system.

Paper I

In Paper I we calculated crude sensitivity and specificity values, with 95% CI[157] for each of the 13 original questions. The cut points for positive response to each question were based on eyeball inspection of response distributions and on prior clinical experience. In order to select a minimal set of questions that best distinguished between prolapse and non-prolapse women the following strategy was adopted: We evaluated the diagnostic value of each question in univariate logistic regression models. Then various combinations of the questions were evaluated in multivariate logistic regression models using stepwise backward elimination to

arrive at a preliminary multivariate model. The stepwise approach was assumed to work well since there were very few missing values in the data. In all multivariate logistic regression models we adjusted for age. Then the effect of collapsing or extending the number of categories for the questions was evaluated in the resulting preliminary multivariate model. To insure selection of the most powerful combinations of questions, we further evaluted the effect of each of the previously eliminated variables in the new preliminary multivariate model before the final model was chosen. Adjusted odds ratio scores from the final logistic regression model were then tested in discriminant analyses for the development of a discriminant criterion according to which the participating women in the Stockholm sample were classified. We calculated positive and negative predictive values in our studied population sample, emphasizing that these values are very much dependent on the prevalence of prolapse among the individuals being investigated.
Kappa scores evaluated reproducibility[158].

Paper II

Age-specific prevalence in 10-year age strata was expressed as the number of subjects with a questionnaire score exceeding our predefined criteria in Paper I, divided by the total number who provided interpretable responses in the respective age stratum. We calculated 95% CI. Statistical testing of trends across age groups and parity groups was performed using the Cochran-Armitage test for trend. The effects of age, parity and history of previous gynaecological surgery were first estimated in univariate logistic regression models with the odds of POP as the dependent variable. The associations were expressed as odds ratios with 95% CI. To disentangle the adjusted effects of age, parity, and previous surgery we also fitted multivariate logistic regression models. Since the effect of age seemed to be non-linear, we further fitted generalized additive models[159]. Nested multivariate models were tested against each other using the deviance as a test for goodness-of-fit. All tests performed are two-sided at the 5 % significance level.

Paper III

Effects of the participants' weight and length (body mass index, BMI, <20, 20-24.9, ≥25) at age 20 years and at investigation, family history for surgery for POP or urinary incontinence

(mother or sister), age at first delivery (15-19, 20-24, 25-29, 30-34, ≥35), weight of largest born child (<4000g, ≥4000 g), length of labour at first delivery (<1 hour, 1-6 hours, 7-24 hours,>24 hours), vaginal tears (ever/never), episiotomy (ever/never), anal sphincter tear (ever/never), instrumental delivery (ever/never), and Caesarean section (ever/never and proportion of all deliveries) were estimated in univariate logistic regression models with the odds of POP prevalence as the dependent variable.The analyses were limited to women with at least one delivery.Associations were expressed as prevalence odds ratios with 95% confidence intervals.To disentangle the independent effects of the variables that were significantly linked to POP, multivariate logistic regression models were fitted for the variables above adjusting for age at investigation (30-39,40-79) and parity (1,2-3, ≥4). At the end a multivariate logistic regression model including all the obstetric variables and adjusting for age and parity was fitted.

Paper IV

Analysis was performed using Fischer´s test exact test, x^2 analysis and multivariate stepwise logistic regression.

Paper V

Descriptive data are presented as absolute and relative numbers of women.
Risks of unfavourable outcome;
I**:** prolapse- or treatment-related symptoms; II: recurrent or persistent anatomical prolapse; or III**:** either or both of I and II were compared in strata of prognostic factors, and relative risks are given with Taylor series 95% confidence intervals[160]. Possible confounding from other prognostic factors, the effects of prognostic factors in continuous form (age and BMI), and the presence of interactions, were evaluated using multivariate logistic regression. To evaluate the importance of the proportion of subjects with unknown outcome, sensitivity analysis was performed, i.e. all subjects with unknown outcome data were considered as either treatment failures or treatment successes.

Ethics

All the studies were approved by the Ethics Committee South of the Karolinska Institute. All the subjects received written information before enrolment.

RESULTS

Association between symptoms and POP, and construction of a questionnaire (Paper I)

Phase I;

A set of 13 questions, often used in clinical situations when discussing possibly symptoms of POP, was handled out to a total of 399 women (**Appendix I)**. In the group women (n=200) with a prolapse (Group 1) 49 % had voiding difficulties (often/sometimes), 18% had to lift the anterior vaginal wall to start or complete voiding (often/sometimes) and 54% had genuine stress incontinence(often/sometimes). Forty-four percent of women with POP and 22.5% of women with no prolapse (n=199, Group 2) had difficulties with defecation (often/sometimes). Of women with POP there were 21% who sometimes used digital manipulation for complete defecation compared with 6% among women with no prolapse (often/sometimes)(Table I).

The crude sensitivity and specificity values and the reproducibility for each of the 13 questions are shown in Table I. The cut-points used for a positive prolapse categorization for each question are given in the table. The sensitivity ranged between 21% (question 10) and 89% (question 4). The specificity ranged between 71% (question 12) and 98 % (question 13 and question 9). The question “Do you have a sensation of tissue protrusion (vaginal bulge) from the vagina” had the highest predictive value for the identification of women with POP.

The kappa values ranged between 0.61 and 0.94 and the majority of questions had kappa values exceeding 0.8, indicating almost perfect agreement between answers given one month apart.

When combining both groups of patients to estimate the importance of each question and its ability to add to the overall predictive ability, the resulting logistic regression model after stepwise elimination of redundant questions resulted in five questions together with age that was forced into the model. A cross-tabulation of test result based on questions 2, 3, 6, 9 and 11 by true diseased status resulted in a sensitivity and specificity of 92.5% and 94.5%, respectively. The positive predictive value in this rather artificial mix of prolapse-positive and negative women was 94.4% and the negative predictive value was 92.6% (Table II)

Table I

Table 1I. Discrimination analyses for sensitivity and specificity for questions 2, 3, 6, 9 and 11 in the final model, women with genital organ prolapse (Group 1) and women without any prolapse (Group 2)

Disease status by discrimination criteria	True disease status Prolapse present	No prolapse	Total
Positive test for symptomatic POP	185	11	199
Negative test for symptomatic POP	15	188	203
Total	200	199	399

Phase II;
The most powerful short set of questions (see statistic methods), was sent to a random sample (n=8,000) of the Stockholm female population aged 30-79 years. Among women whose scores were indicative of symptomatic genital organ prolapse, we randomly selected 206, who were invited to a standardized gynecological examination following the principles given above (POPQ). Likewise, we randomly selected 206 women whose answers indicated absence of genital organ prolapse. The participation in this second phase of the investigation was 79% (Group A, n=162) and 58% (Group B, n=120), respectively, among those with and without a positive questionnaire result.

The POPQ prolapsed stages in Group A were as follows: stage 0 1.9%; stage I 24.1%; stage II 59.3%; stage III 11.7% and stage IV 3.1%. In Group B stage 0 was observed in 33.3%; stage I in 48.3%; stage II in 17.5%; and stage III in 0.8%. No one in this group had stage IV prolapse. The sensitivity and specificity values were 66.5% and 94.2%, respectively when prolapse was defined as stage I-IV. Most missed cases had stage I prolapse (72%) (Table III). If prolapse had been defined as stage II or higher according to POPQ, the sensitivity of our questionnaire would increase to 84.5% (95% CI 77.7-89.5) while the specificity would have dropped to 70.0% (95 % CI 62.0-77.0). The corresponding positive and negative predictive values would be 74.1% and 81.7%.

Table III. Discrimination analyses for sensitivity and specificity for questions 2, 3, 6, 9 and11 in phase two, the screening study, subjects defined as symptomatic prolapse (Group A, n=162) or symptom-less (Group B, n=120) .Stage 1-IV classified as prolapse, stage 0 absence of prolapse

Disease status by questionnaire	True disease status Stage I-IV	Stage 0	Total
Group A	159	3	162
Group B	80	40	120
Total	239	43	282

Prevalence and risk factors for symptomatic pelvic organ prolapse (Paper II)

Of 5489 women (from 8 000 sampled women) included in the study population providing adequate information, 454 women were identified and gave self-reports consistent with POP, corresponding to an overall prevalence of 8.3% (95% CI 7.3-9.1%)

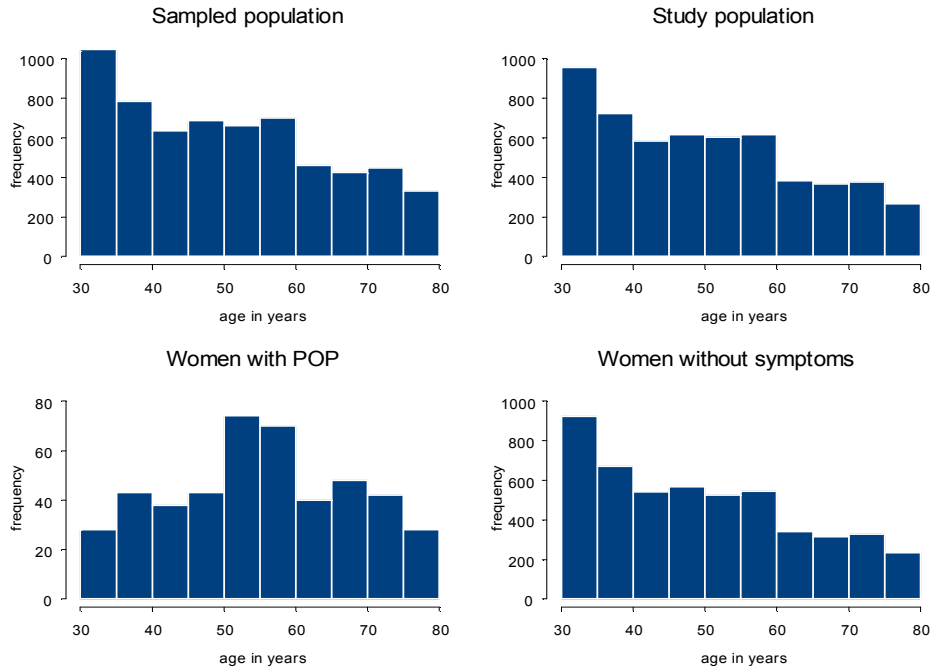


Figure 10. Age of women in the sampled population (N=8000), study population (N=5489), women with positive test for symptomatic POP (N=454) and negative test (N=4988)

The prevalence rose with increasing age but leveled off after menopause; among women 30-39 and 40-49 years old it was 4.1% and 6.2%, respectively, and in the age-groups 50-59, 60-69, and 70-79 years it was 11.8%, 12.2%, and 11.0% (Table IV). Using the 30-39 year olds as the reference, the unadjusted odds ratio of POP increased to around 3 after age 50 and

remained on this level among those who were older than that. The increasing age trend was statistically significant (p-value for the Cochran-Armitage test <0.001).

The number of full term pregnancies was even more strongly linked to POP prevalence (Table IV); the prevalence odds increased almost 4-fold between women with no and those with one full term pregnancy. Then, the odds increased monotonically to more than 10 among women with 5 or more pregnancies. The independent effects of age and number of births were modeled with bivariate logistic regression. There was a two-fold gradient in odds of POP with age when adjusting for parity and an eight-fold gradient in odds of POP with parity when adjusting for age.

Previous surgical procedures for prolapse and/or incontinence, and, in fact, any gynaecological laparotomy, were positively associated with current presence of symptomatic POP. Among 1187 women who had undergone any gynaecological laparotomy, 123 (10.4%) reported current POP (OR=1.4, 95% CI 1.1-1.7, relative to non-operated). This excess, however, disappeared after adjustments for age and number of full term parities .Twenty-six (31%) out of 84 women who had undergone any incontinence operation reported symptomatic POP, corresponding to a prevalence OR of 5.2 (95% CI 3.2-8.3) relative to women who had not undergone incontinence surgery. After adjustments for age and number of full term parities, the OR fell to 3.5 but remained statistically significant (95% CI 2.2-5.7). No less than 45 (42%) out of 107 who had previously undergone surgery for prolapse reported symptoms consistent with current POP (prevalence OR=8.8, 95% CI 5.9-13.1 relative to women without prior prolapse surgery). The OR was also high after adjustment for age and number of full-term parities (6.1; 95% CI 4.0-9.1).

Table IV. Prevalence of symptomatic pelvic organ prolapse (POP) by age, parity, and previous history of gynaecological surgery. Prevalence odds ratios (OR) with 95% CI derived from univariate logistic regression mode.

Factor	Observed cases with prolapse	Prevalence %	95%CI	OR	95% CI
Age group					
30-39	62	4.1	3.2-5.2	1.0	Ref.

40-49	75	6.2	5.0-7.7	1.6	1.1-2.2
50-59	142	11.8	10.1-13.7	3.2	2.3-4.3
60-69	97	12.2	10.1-14.7	3.3	2.4-4.6
70-79	78	11.0	8.9-13.5	2.9	2.1-4.1
Term parity					
Missing	1				
No term pregnancy	35	2.4	1.7-3.3	1.0	Ref
1	95	8.8	7.2-10.6	3.9	2.6-5.8
2	185	9.8	8.6-11.3	4.1	3.1-6.4
3	86	12.2	10.0-14.8	5.6	3.8-8.4
4	32	15.9	11.5-21.6	7.7	4.6-12.7
>4	20	20.8	13.9-30.0	10.7	5.9-19.3
Any gynaecological laparotomy	123	10.4	8.8-12.2	1.4	1.1-1.7
Any incontinence procedure	26	31.0	22.1-41.5	5.2	3.2-8.3
Prior surgery for genital prolapse	45	42.1	33.1-51.5	8.8	5.9-13.1

The number of women who described any (often/sometimes/infrequently) urinary leakage during physical activities, and any urge incontinence was 3444 (63.2%, 95% CI 61.9-64.4%) and 2756 (50.5%, 95% CI 49.2-51.8%), respectively. The prevalence of frequent (equal to the "often" response alternative) stress incontinence was 8.8% (95% CI 8.1-9.6%) and of frequent urge incontinence 5.8% (95% CI 5.2-6.5%).Out of the 454 women with POP, 37.4% had either, or both types of incontinence.

The prevalence of both types of urinary incontinence increased with age, but while it tended to increase monotonically for urge incontinence (Figure 11) the pattern for stress incontinence was similar to that seen for POP, with a knee in the prevalence curve coinciding approximately with menopause (Figure 12).

Figure 11. Prevalence of urge incontinence according to age group.
Black=often;hatched=sometimes;white=occasionally

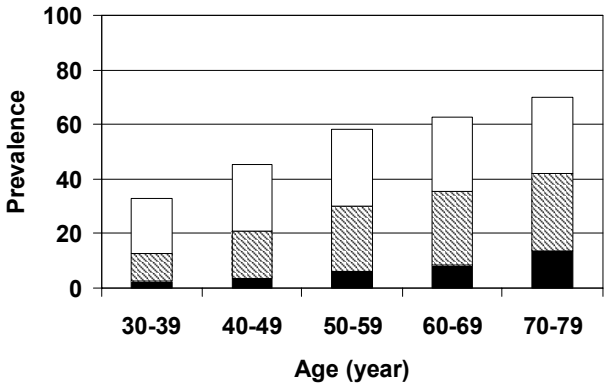
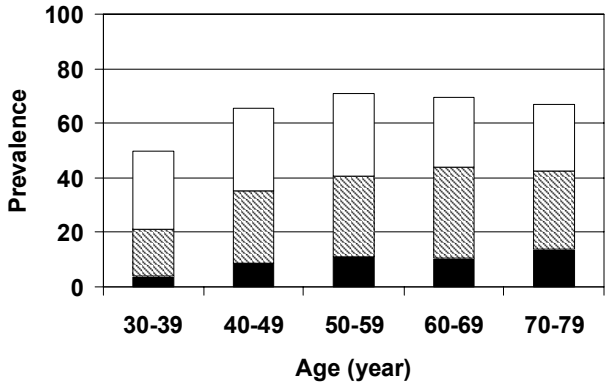


Figure 12. Prevalence of stress incontinence according to age group.
Black=often;hatched=sometimes:white=occasionally



The presence of the two types of frequent urinary incontinence overlapped substantially (Figure 13). The prevalence of urinary incontinence of both types simultaneously was 3.2% (95% CI 2.7-3.6%), of isolated frequent urge incontinence 2.7% (95% CI 2.3-3.1%) and of isolated frequent stress incontinence 5.7% (95% CI 5.1-6.3%). Moreover, there was a considerable overlap between occurrence of urinary incontinence and POP (Figure 13). Of the 454 women classified as having POP, 170 (37.4%) had either or both types of incontinence; 130 (28.6%) had frequent stress incontinence and 102 (22.5%) frequent urge incontinence. Frequent stress and urge incontinence was reported by 7.1% (95% CI 6.4-7.8%) and 4.3% (95% CI 3.8-4.9%), respectively, of the 4988 women who were classified as not having POP.

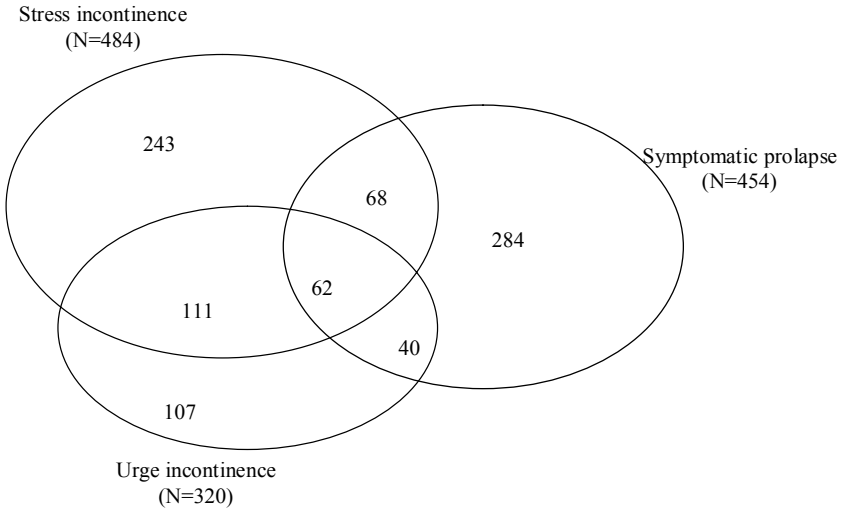


Figure 13. A Venn diagram describing the overlap between symptomatic POP, frequent stress incontinence and frequent urge incontinence

Obstetric risk factors for symptomatic POP (Paper III)

A detailed questionnaire was sent out to a group of 859 women, of which 454 were classified as cases and 405 as controls. It was returned by 656 women, in total 77 %. Prevalence OR for symptomatic POP among women with at least one childbirth was 5.1 (95% CI 3.1-8.3) relative to nulliparous women (656 responders).Among women who had had at least one delivery (n=554) it was confirmed, by univariate analysis, that attained age and parity at time of the study were strongly linked to POP prevalence (Table V). The age and parity distribution, BMI at 20 years old as well as at the time of investigation and a family history of surgery (mother or sister operated on for POP or urinary incontinence) are shown in Table V.

Table V. Distribution of demographic data between women with symptomatic POP (cases, n=322) and women without prolapse symptoms (controls, n=232) with at least one delivery.

Variables	Cases	Controls	OR	95 % CI	OR*	95 % CI*
Attained age at survey investigation						
30-39	39	52	1.0	Ref.	1.0	Ref
40-40	55	34	2.2	1.2-3.9	2.0	1.1-3.7
50-59	106	69	2.0	1.2-3.4	2.0	1.2-3.4
60-69	77	44	2.3	1.3-4.1	2.2	1.3-3.9
70-79	45	33	1.8	1.0-3.4	1.7	0.9-3.2
Term parity						
1	65	73	1.0	Ref.	1.0	Ref
2	157	107	1.6	1.1-2.5	1.7	1.1-2.5
3	72	43	1.9	1.3-8.1		
>3	28	9	3.5	1.5-7.9	3.3	1.4-7.5
Family history of pelvic floor dysfunction surgery	223	195	3.2	1.8-5.6		
No family history	66	18	1.0	Ref		
BMI at 20 years old						
<20	119	88	1.0	0.7-1.4	1.0	0.7-1.5
20-24.9	171	127	1.0	Ref	1.0	Ref
25-29.9	11	5	1.6	0.6-4.8	1.3	0.4-4.1
≥30	2	1	1.5	1.1-16.8	1.4	0.1-16.4
BMI at survey investigation						
<20	19	34	0.5	0.3-0.9	0.6	0.3-1.1
20-24.9	137	121	1.0	Ref.	1.0	Ref.
25-29.9	117	55	1.9	1.3-2.8	1.7	1.2-2.6
≥30	46	19	2.1	1.2-3.8	2.0	1.1-3.7

*univariate adjusted for attained age (30-39; 40-79) and parity (1; 2-3,>3)

Univariate and simple age- and parity-adjusted analyses of delivery data revealed that neither age at first delivery nor length of labour at first delivery was statistically significantly associated with subsequent presence of symptomatic POP (Table VI).

Any delivery of large babies was statistically significant in the univariate analysis. The prevalence OR for symptomatic POP among those who had given birth to a baby weighing >4000 grams compared to those who had not was 1.5 (95% CI 1.1-2.4). Women who had a history of repeated deliveries of children weighing more than 4500 grams had a more than 3-fold excess in prevalence odds, however, this was based on no more than 8 exposed cases and 2 controls, and was therefore not statistically significant. After adjusting for age and parity, the association between large babies and symptomatic POP became attenuated and no longer statistically significant. BMI at age 20 years was only weakly, and non-significantly, linked to POP prevalence.

Stretching and tearing during the first and second phase of the delivery, reflected by either a history of episiotomy, extensive vaginal tear or anal sphincter tear, had a twofold increase in odds of having symptomatic POP.

Abdominal delivery appeared to be protective against symptomatic POP as a binary variable (yes/no). One or more abdominal deliveries corresponded to an odds ratio of 0.6 (95 % 0.3-0.8). The larger the proportion of all deliveries that were carried out as Caesarean sections, the lower were the prevalence odds (>50 % was associated with an age- and parity adjusted OR of 0.4).

To disentangle the independent effects of significant obstetric factors identified in the univariate analyses, multivariate models with weight of largest infant (<4000, ≥4000 g), rupture/episiotomy, BMI at 20 years old, instrument delivery, length of labour at first delivery, age at first delivery and abdominal delivery were entered in multivariate logistic regression models that were adjusted for age (30-39, 40-79 years) and parity (1, 2-3, ≥4). Several models were tested, stepwise models deleting or including the most significant variable one at a time. Since some of the variables were not complete, the final models were tested in the largest subset possible and by including some of the most significant variables

from the univariate analyses. The final model consisted of the variable of any rupture (vaginal or anal sphincter tear)/episiotomy adjusted for age and parity.

Table VI. Univariate as well as age- and parity-adjusted analyses of the associations between specific events at delivery and subsequent presence of symptomatic POP (322 cases, 232 controls). Prevalence odds ratios (OR) with 95 % confidence intervals (CI).

	Cases	Controls	OR*	95% CI*	OR**	95 % CI**
Caesarean delivery						
No	294	194	1.0	Ref.	1.0	Ref.
Yes	28	38	0.5	0.3-0.8	0.6	0.3-0.9
Proportion caesarean of all deliveries						
0-49 %	301	198	1.0	Ref.	1.0	Ref.
50-100 %	19	30	0.4	0.2-0.8	0.4	0.2-0.8
Instrument delivery						
No vacuum delivery	267	190	1.0	Ref.	1.0	Ref.
At least one vacuum delivery	46	34	1.0	0.6-1.6	1.0	0.6-1.5
No forceps delivery	298	214	1.0	Ref.	1.0	Ref.
At least one forceps delivery	9	6	1.1	0.4-3.1	1.1	0.3-2.9
Extensive vaginal rupture (ever)						
No	138	137	1.0	Ref.	1.0	Ref.
Yes	133	61	2.2	1.5-3.2	2.1	1.4-3.1
Any anal sphincter tear (ever)						
No	230	196	1.0	Ref.	1.0	Ref.
Yes	26	13	1.7	0.9-3.4	1.6	0.8-3.3
Episiotomy (ever)						
No	144	128	1.0	Ref.	1.0	Ref.
Yes	137	82	1.5	1.0-2.1	1.4	1.0-2.0
Any rupture (anal sphincter or vaginal)						
No	153	158	1.0	Ref.	1.0	Ref.
Yes	143	65	2.3	1.6-3.3	2.2	1.5-3.2
Any rupture or episiotomy						
No	120	116	1.0	Ref.	1.0	Ref.
Yes	197	111	1.7	1.2-2.4	1.6	1.1-2.3

* univariate

** adjusted for attained age and parity

Long-term results of surgery for genuine stress incontinence (Paper IV)

One hundred and sixty-nine women were invited to this follow-up study, of whom 131(78 %) were willing to attend. There few serious complications peri- and postoperatively. There was one woman with massive bleeding where the operation had been combined with a hysterectomy and one woman had deep-venous thrombosis followed by a pulmonary embolism. The most common postoperative complication was a urinary infection (n=50). No prophylactic antibiotics were administrated before operation. All patients met the surgeon 6 to 8 weeks after the operation. According to the files at that time, 113 (86%) women were subjectively continent regarding GSI, 15 (11%) had improved and 3 (2%) were still incontinent. Sixty-six (50%) women complained of urge with or without leakage at the visit.

Long-term follow-up visit (5-11 years after surgery);

In order to validate the outcome at follow-up visit three different end points were constructed:

1. *Patient satisfaction with the outcome as determined by protocol*. One hundred and nine women (83%) were satisfied with the results of the operation, 22 (17%) were not.
2. *Subjective cure rate in terms of urinary leakage as determined by protocol*. When the women described their situation according to symptoms of urinary leakage, 54 % were completely dry and 30 % were still using sanitary pads (Table VII).
3. *Objective cure rate determined with a provocative stress test.* The cure rate for stress incontinence was 93 % (122 women). Only 9 women showed urinary leakage during the test. Among these there were 5 women who had had a previous operation for stress incontinence.

Table VII. Subjective cure rate. Women's description at long term follow-up visit

Outcome	Number	Urge incontinence	Mixed incontinence	GSI	urgency
Continent	71	0	0	0	12
Small leakage	46	41	4	1	0
Frequent leakage	14	0	13	1	0
Total	131	41	17	2	12

A total of 33 women (25%) developed signs of POP. The most common site was posterior vaginal wall prolapse (18 women). Twenty-four women described voiding difficulties with a slow stream. Mean residual volume was 31 ml (range 0-200 ml).

In order to find prognostic factors for a negative outcome in terms of subjective and objective cure rate the women were divided into two groups according to cure rate, continent (n=71) and still incontinent (improved or failure, n=60). Using multivariate logistic regression analysis, a comparison between continent and incontinent groups found that a low urethral pressure preoperatively did not influence the subjective cure rate, nor did age or chronic disease. A previous operation for incontinence was not a risk factor for a negative outcome. The preoperative symptom of mixed incontinence was the only negative prognostic factor for a successful outcome according to subjective cure rate, but had no impact on objective cure rate or satisfaction of the operation. The women who were not satisfied (n=22) with the operation complained of urge incontinence.

The cure rate did not decline 5 years postoperatively (Figure 14).

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Figure 14. Results year-by-year. Outcome was the same whether 6 or more year had passed after operation.

Long-term results of surgery for POP (Paper V)

In total 269 women were invited to this follow-up study, of whom 128 (47%) attended the follow-up visit (10-12 years after the operation). Background data including age, parity and severity of the prolapse are shown in Table VIII. The subjects not attending the follow-up visit were significantly older, they had a third-degree prolapse and a vaginal hysterectomy was performed more often than for women attending follow-up. Complications at operation were few in both groups.

Table VIII. Preoperative data from medical records of 259 women operated for genital prolapse 1988-1989.

	Attended follow-up visit n=128	**%**	**Did not attend follow-up n=131**	**%**
Mean age(range)	65 (39-83)		70(37-86)	
Mean parity (range)	2.2 (0-7)		2(0-5)	
Preoperative defects				
Cystocele	123	96	99	75
Rectocele	107	84	91	69
Cervix elongation	64	50	54	41
Eneterocele	5	3.9	6	4.5
Uterine prolaspe	60	47	60	46
Vault prolapse	3	2.3	0	
Preoperative degree of prolapse				
I	69	54	53	40
II	46	37	42	32
III	13	10	36	27
Operation performed				
Manchester procedure	92	71.8	100	76.4
Anterior and posterior colporraphy	19	14.8	13	9.9
Ant. colporaphy combined with cervix ampuation	5	3.9	0	
Posterior colporaphy combined with cervix ampuation	1	0.8	0	
Vaginal hysterectomy	6	4.7	17	12.9
Colporaphy and enterocele repair	4	3.1	1	0.8
Abdominal vaginosacropexy	1	0.8	0	

The most common functional symptom of POP preoperatively recalled from the records were among all women (n=259);

1. Local symptoms such as vaginal pressure or heaviness or vaginal bulge, n= 236(91 %)
2. Urinary symptoms; feeling of incomplete emptying of bladder, n=132 (51%); urinary incontinence, n=80 (31%)
3. Bowel symptom (difficulty with defecation), n=54 (24%)

At the follow-up visit, in median 11.3 years after surgery, both subjective and objective outcome of surgery was analysed. An unsatisfactory anatomical outcome was not necessary associated with symptoms. Fifty-six women had anatomic signs of a recurrence of prolapse defined as stage II or more, according to the POPQ system[91]. Thirty-eight of these women had functional symptoms or side-effects of operation. Only 41 (32%) women were subjectively and objectively cured, with no recurrence and no symptoms (Table IX).

Table IX. Subjective and objective outcomes of surgery

	Functional symptoms or side-effects of operation		
Anatomical signs of persistence or recurrence of POP	Yes (%)	No (%)	Total (%)
Yes (%)	38 (30)	18 (14)	56 (44)
No (%)	31 (24)	41 (32)	72 (56)
Total (%)	69 (54)	59 (46)	128 (100)

At the time of surgery 82 (64%) women were sexually active and at the follow-up visit 21 of them complained of introital dyspareunia whereas another seven women were unable to have intercourse at all after the operation due to pain.

Twenty-four women in the follow-up group had a history of genuine stress incontinence before initial operation, noted in the medical record. Six of these women were cured. Another 29 developed de novo genuine stress incontinence (23%). Thirteen women complained of faecal incontinence at follow-up out of which 3 women had reported faecal incontinence before operation and 24 women had incontinence for flatus. Notes of anal incontinence

among the women were seldom made in the records. The presence of anal incontinence could only be evaluated at follow-up visit (Table X).

Table X. Symptoms of pelvic floor dysfunction in the follow-up visit, women with a recurrence of genital prolapse=56, women without a recurrence=70, total group=128)

Symptoms	***Recurrence n=56 (%)***	***No recurrence n=72 (%)***	***Total group n=128 (%)***
Urinary symptoms:			
Stress incontinence	11 (19.6)	18 (25.7)	29 (22.6)
Urge incontinence	30 (53.4)	40 (57)	70 (54.7)
Feeling of incomplete emptying	4 (7.1)	1 (1.4)	5 (3.9)
Bowel symptoms:			
Difficulty with defecation	17 (30.4)	15 (21.4)	32 (45.7)
Incontinence of flatus	16 (28.6)	8 (11.4)	24 (18.8)
Incontinence of solid stool	5 (8.9)	8 (11.4)	13 (10.2)
Sexual symptoms:			
Pain with coitus	9 (16)	10 (14.3)	19 (14.8)
Local symptoms:			
Vaginal pressure	2 (3.6)	0	2 (1.6)
Vaginal pain	6 (10.7)	0	6 (4.7)
Awareness of lump	10 (17.9)	0	10 (7.8)

Values are n(%)

The possible associations of preoperative factors associated with unsatisfactory outcomes, were evaluated using univariate and multivariate analysis. In univariate analysis, previous

POP surgery and urge incontinence were associated with an increased risk of adverse outcome. Multivariate logistic regression analyses showed that a complicated delivery and urinary incontinence prior to surgery was significantly associated with recurrence and a complicated delivery also with residual symptoms.

If perfect results had been obtained in all women who did not undergo follow-up examination, the objective and subjective cure rate would be 73% and 79%, respectively. If the results had been adverse overall, the outcome in all women who did not undergo follow-up examination would be 23% and 26%, respectively.

GENERAL DISCUSSION

Symptoms of pelvic organ prolapse

Pelvic organ prolapse can be defined in terms of physical and anatomical findings or symptoms. Research in this field has for years been hampered by a lack of widely accepted definitions. In 1996, the International Continence Society published a standardized system of terminology for description of POP, the pelvic organ prolapse quantification system (POPQ)[91]. However, while aberrations of pelvic floor anatomy can now reproducibly be described, lay women will only note – and potentially suffer from – POP that gives rise to symptoms. This leaves a diagnostic problem since the anatomical stage of POP is not invariably related to symptoms[11 109 110].

Pelvic organ prolapse is often accompanied by urinary symptoms[5]. Urinary incontinence commonly co-exist with POP[4 161 162]. Urinary symptoms in women with POP also include voiding dysfunction such as a feeling of incomplete emptying, hesitancy, prolonged urinary stream and urinary retention. Voiding difficulties and urinary incontinence were common findings in this study in association with POP (Paper I-II). This is in line with another study, showing that more than two-thirds of women with symptomatic POP reported some degree of frequency or/and urgency and that also symptoms of voiding dysfunction were commonly reported and nearly half of the women reported difficulty in emptying their bladder[109]. Urinary symptoms were also noted frequently, among women who should undergo surgery for POP (Paper V).

It has been reported that 76 % of women with POP have defects of the posterior vaginal wall[14], and also that women with posterior vaginal wall prolapse were more likely to have difficulty with defecation than women without prolapse[102 110]. However, many bowel symptoms have been linked to posterior vaginal wall prolapse, with little data to establish this relationship[102] and it was reported that of 76 % of asymptomatic nulliparous volunteers had small rectoceles on defecography studies[163]. In this study, the question ”Does it happen that you have difficulties with emptying your bowel” had no predictive value in our study since bowel symptoms were common among women with POP, but also frequently among women without any prolapse (Paper I).

Constipation is a common finding in women with POP[126 128] and it is suggested that constipation appears to be a major aetiological or associated factor in almost all women with symptomatic POP[82]. However the definition of constipation may vary and it was found that young adult's not seeking health care defined constipation in a variety of ways: straining at stool (52%), hard stools (44%), wanting to evacuate but being unable to (34%), infrequent stools (32%), abdominal discomfort (20%), incomplete evacuation (19%), too much time on the toilet (11%)[164]. In constipated women the frequency of each symptom increased, but the proportions of those reporting each symptom remained the same. From these studies it seems that bowel symptoms could not be used as indicative of POP.

Early in history it was postulated that a dominant symptom of POP was that women were aware of local symptoms from the vagina as a sensation of tissue protrusion or an observation of a mass (see introduction). This was also concluded in a study from 1947 among American women with POP[30]. It is suggested that 80% of patients referred to hospital with POP complain of "something coming down"[165], and it is also shown that mechanical symptoms from the prolapse seems to be most troublesome in patient's daily lives[110]. Further studies are in line with this[11 109 110] and in this study the question "Do you have a sensation of tissue protrusion (vaginal bulge) from the vagina" carried almost all of the predictive ability of all initial 13 questions (Paper I). The strength of this question is probably due to the fact that all of the cases in the first phase of the study (Paper I) had a symptomatic prolapse of stage II or higher, and also that local symptoms increase with increasing POPQ stage[13,14].

When the questionnaire was tested about symptoms of POP in the survey investigation (phase II) the sensitivity dropped, but the specificity remained at a high level. The aim was to identify women with clinically significant symptomatic prolapse, and most of the missed cases had stage I prolapse. Although the course of clinically silent stage I prolapse in non-patients is essentially unexplored, such prolapse appears to be exceedingly common in the population[8 12 93], and perhaps most of these women will never develop clinically important disease.

It has been concluded that women with POP experience symptoms that do not necessarily correlate with compartments-specific defects. Increasing severity of POP is weakly to

moderately associated with several specific symptoms that are related to urinary incontinence and voiding, defecatory and sexual dysfunction[109].

Prevalence of urinary incontinence

Urinary incontinence is a common, but often unreported symptom among women. Firm data about prevalence in the general population show wide variation.[2 166-169], partly due to different definitions of urinary incontinence and different populations of women studied. The aim in Paper I was to validate questions for identification of symptomatic POP. We found that questions about urinary symptoms were important to identify POP probably since UI often exists with POP.

In our final short questionnaire used in this cross sectional study (**Appendix II**) there were two questions about urinary incontinence; "Do you suddenly feel urge to go to toilet, and then accidentally leak urine? "and "Do you leak urine when you are coughing, sneezing or lift heavy? ".The alternative responses were; often, sometimes, infrequently or never. Limitations with these questions are unclear definition of an alternative answer according to frequency. Is often once a day or once a week?

Any urinary leakage during physically activities, and any urge incontinence were common and the prevalence of frequent (equal to the "often" response alternative) stress incontinence was 8.8% and of frequent urge incontinence 5.8%. The prevalence of both types of urinary incontinence increased with age, but while it tended to increase monotonically for urge incontinence the pattern for stress incontinence was similar to that seen for POP, with a knee in the prevalence curve coinciding approximately with menopause. The increase with age for the prevalence of urinary incontinence is in line with other studies[17 166 170], but the reported prevalence for any urinary incontinence is higher [17 167 168 171]. In a Swedish study[172] performed with 725 women 39 % reported occasional urinary incontinence before pregnancy and in another Swedish population-based study a high rate of women reported any incontinence, 52% for women at the age of 60 years[173].

If we add together the number of women who described the leakage as often or sometimes, the prevalence for stress incontinence was 34.5% and for urge incontinence 25.5%, which is

in line with another Swedish population-based study (women 20-59 years old) reporting a prevalence of urinary incontinence of 28%[171] .

Prevalence of POP

Firm data about the incidence and prevalence of POP are sparse and inconsistent[8 10 12 13 15 16 174]. There has not been any specific symptom complex to define POP in contrast to urinary incontinence, and it is technically challenging to design epidemiological studies. Thus, a set of questions was constructed and validated to enable a standard questionnaire to be set for identifying POP. The purpose of our cross-sectional survey (Paper II) was to estimate the prevalence of symptomatic POP in a Swedish urban population.An overall prevalence of 8.3% was noted. The prevalence rose with age up to age around 50, but thereafter there was no further increase.

In other epidemiological studies that used self-reports[15 175] the prevalence was of a similar magnitude as in our study despite vast cultural differences. The latter studies are, however, limited by the fact that the questions were not validated. In yet other studies the prevalence estimates were based on women attending outpatient clinics[3 4], being admitted to hospital for surgery of POP[10 14], or volunteering in various menopausal studies[4 6 16 18 21] thus making inferences to the general population difficult. Most of these studies were not POPQ-based.

The vast variation in reported prevalence of anatomical POP, ranging from 2.4%[12] to 50%[13] may conceivably be explained both by varying selection forces and by variation in examination techniques. Samuelsson *et al*[8] examined a representative sample of a Swedish female population. They reported a considerably higher prevalence of prolapse (any degree) than observed in our study, but most prolapse-positive women had minor abnormalities and only a minority had symptoms. As the POPQ was not used, comparability with our study is hard to establish.

Although POPQ has been validated[92 93 176], it has been used in few population-based studies, and any population-based study should not only take anatomical changes into consideration but most importantly the women´s symptom as well..

Risk factors associated with POP

The aetiology of POP has been discussed for four thousand years[7] and delivery trauma and heavy lifting was suggested already B.C. The Manchester school suggested five factors which they considered to cause POP[32]. These were damage due to childbirth, heavy hard work, tissue weakness, postmenopausal atrophy and increased intra-abdominal pressure.

Several studies have shown that parity and age have a strong association with POP[8 10 14-16 174 177]. In the cross-sectional survey with 5489 women (Paper II) it was found that the number of full-term parities was a stronger determinant of symptomatic POP than age. However, since symptomatic POP was present in 2.4% of nulliparous women, childbirth was not a necessary condition for the development of symptomatic POP.

Although age is widely recognized as an important determinant for the prevalence of POP, few studies have provided detailed and precise data by pre- and postmenopausal age. Thus, the combined previous literature can neither confirm nor refute the finding of a distinct knee on the age-prevalence curve coinciding approximately with the age of menopause. A similar knee has been observed in the age-prevalence curve for stage II prolapse among women seeking routine gynaecological health care [13], whereas stage III prolapse continued to increase after age 50. Other studies were unable to confirm a change in trend around age 50, but they were either based on consulting patients[14 16 178] who may not be representative of the population at large, or did not have a sufficient number of observation points above age 50 to clearly refute a plateau[8].

Previous surgical procedures for prolapse and/or incontinence were positively associated with current presence of symptomatic POP in our study (Paper II). It has been reported that one women out of three, surgically treated for POP or urinary incontinence will require reoperation[14]. In a case-control study it was shown that a previous surgical procedure was associated with high risk of developing a further POP[174]. Also in the follow-up study (Paper V) in this thesis a high anatomic recurrence after surgery was noted.

Over-weight has been shown to be associated with genuine stress incontinence[168 179] but there was no association between over-weight and POP in a case-control study[174] nor in a population-based study[8]. In this study (Paper III), overweight (BMI>25) was associated with

an approximately twofold increase in the odds of having symptomatic POP, compared to "normal", after adjusting for age and parity. This is in line with another study, which reported a three-fold increased risk of pelvic floor disorders, if BMI was over 26[180]. The very lean (BMI<20) tended to have low prevalence odds for POP.

The relationship between congenital factors and POP has not been documented in an epidemiological study. It was reported that women with urinary incontinence and POP have a reduction in collagen contents [65-68]. If this reduction is the reason for a weakness in the supportive ligaments and fascia and further a weakness that could be inherited, could only be speculated about[65]. Family history of surgery for urinary incontinence and POP seem to have a strong association with increased risk of symptomatic POP in this study (Paper III). The odds of having symptomatic POP were three-fold higher among women whose mothers or sister had undergone POP or urinary incontinence surgery than among women without such a family history. However, it is unclear how the association between family history for surgery and symptomatic POP should be understood in this study. Maybe women with prolapse related symptoms and participating in a study about symptoms of POP are more aware of their mother´s and sisters surgical procedures for PFD.

The controversy over caesarean versus vaginal birth with regard to the pelvic floor trauma is still in progress. Abdominal delivery was protective against symptomatic POP in this study (Paper III), in line with other studies [181-183]. Caesarean delivery was also protective for prevalence of urinary incontinence three months after delivery[184]. Symptoms of prolapse were significantly less reported from women with Caesarean delivery compared with women with vaginal delivery.[15]. Another study, on the other hand, reported that Caesarean delivery during active labour and vaginal delivery had similar effects on maternal pelvic support, but this study was mainly concerned with acute effects (6 weeks postpartum)[185]. In the absence of randomized controlled trials, it cannot be unequivocally determined whether the procedure *per se* accounts for the entire protective effect or if women who are considered for Caesarean section have a low baseline risk of POP. Given the often complicated obstetric situation that is alleviated by the use of Caesarean section, the latter explanation appears less likely.

The absence of association between instrumental delivery and symptomatic POP in this study (Paper III) is in conflict with indications obtained in some studies[15 186-188], but receives support from others[186].

The effect of episiotomy on the pelvic floor is a matter of debate. An association for symptomatic POP was found in this study when an episiotomy was done. An association between episiotomy and diminished pelvic floor strength and an increased risk of third- and fourth-degree tears but not with subjective symptoms of bulging three months post partum has been noted[189]. The risk of rectal injury increased with midline episiotomy increased the risk[190] and women who had midline episiotomy were eight times more likely to suffer a severe laceration than women who did not undergo an episiotomy[191]. Episiotomy was associated with third-and fourth-degree perineal lacerations [192] and a Swedish study[193] found that women delivered after episiotomy had weak pelvic floor muscle strength compared with women delivered without any episiotomy.

Thus, there was a significant association between symptomatic POP and any rupture (vaginal or anal sphincter tear) or/and episiotomy. The links between anal sphincter lacerations and subsequent anal incontinence is well established[15 54-57 182 186-188 194]. This epidemiological investigation is one of the few that has established the magnitude of the excess risk for POP, linked to stretch-associated obstetric events in the unselected parous female population

It has for years seemed reasonable to assume that the size of the baby is closely linked to the degree of straining, stretching and compression. An association between high birth weight and symptomatic POP in univariate analysis, found in this study is in line with results of several studies [59 174 192]. However, after adjustment for age and parity this association was not significant. Progretto Menopausa Italia Study Group[16] did not find any association between the vaginal delivery of children with a weight over 4500 g and uterine prolapse and Combs *et al*[188] found no association between high birth weight and lacerations.

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Surgical treatment for genuine stress incontinence and POP

Many different surgical procedures have been described during the last hundred years for the treatment of GSI and POP. However, there is no agreement as to which of them is most effective.

Abdominal colposuspension has been an effective procedure to treat stress urinary incontinence[113] and has been the gold standard for many years, and was so when the long-term follow-up study was planned (Paper IV). The objective cure rate for correcting GSI was high but the subjective cure rate was low in this study. This may be due to a rather high number of women included with mixed incontinence symptoms preoperatively. De novo urge symptoms after abdominal colposuspension have been reported to occur in up to one in five women [113 195 196], which is comparable to the results in this study. The only significant prognostic factors for remaining incontinent were urge symptoms preoperatively. This is in line with other studies[113]. Thus urge symptoms should be considered before surgery.

In total 25% developed signs of POP in our study, in line with other studies[124]. However, it was concluded at an ICS meeting in 2001[124],

> "*that there is no evidence to support the view that surgery to prevent prolapse performed at the time of incontinence surgery prevents the development of prolapse in future. There is some evidence to suggest that prolapse, when present at time of incontinence surgery, is associated with a poorer outcome for cure of stress incontinence".*

Nowadays, when it is considered that the sling procedure appears to be as effective[118], this will probably replace the colposuspension as the gold standard since the sling procedure is easy to learn and entails a short time of recovery and few complications for the patient[197]. It has been shown that at six weeks after surgery, there are significant differences in emotional outcome as well as social and physical function and vitality, after TVT compared with colposuspension[118]. These differences between the two groups remain at the two years follow-up. However, colposuspension may be considered as an alternative to the sling-procedures. Open colposuspension has a low rate of perioperative complications[198] , can be combined with hysterectomy and is effective in restoring an anterior vaginal wall prolapse.

Pelvic organ prolapse is the most common indication for hysterectomy in women >55 years old in the United States[199]. The mean age of women undergoing prolapse surgery in 1997 (U.S.) was 54.6 years[200]. Prolapse surgery was not common for young women< 30 years old and for elderly women >80 years old. In this study (Paper V) mean age was 10-15 years higher among women operated on for POP, 1986-1988 (65 years respective 70 years). The overall complication rate was 15%, in line with the American study, where 15.5% of the

women had complications and bleeding and infections accounted for the majority of complications. Thus, prolapse surgery has low rates of serious complications independent of age.

Surgical treatments aim to restore the normal anatomy as far as is possible[124]. The aims of surgery in the management of POP include (Cochrane recommendations 2004)[201]:

1. The restoration of normal vaginal anatomy
2. The restoration or maintenance of normal bladder function
3. The restoration or maintenance of normal bowel function
4. The restoration or maintenance of normal sexual function

Local symptoms were described in the medical records as an indication for surgery for POP for most of the women (Paper V). There were few women with an anatomical recurrence of prolapse (stage II or more), who complained of vaginal protrusion at the follow-up visit. It is suggested that the goal of surgery for POP is to effect changes in anatomic structure that provide patients with relief of symptoms[202] , and it appears that many women are satisfied with the result of the surgical procedure if the sensation of a vaginal bulge is resolved[138]. These women may be categorized as “anatomical failures” but are in fact satisfied with their post-surgical results.

Due to side effects after surgery it is considered wise to treat only symptomatic prolapse[124]. Treatment of POP may result in new urinary, bowel or sexual dysfunction symptoms. Surgery for POP may also lead to the development of GSI [14 203]. The best way to predict or avoid this is not concluded[124]. Of the women who underwent prolapse surgery in the United States, in 1997, 21% also had incontinence surgery. If a continence procedure is combined with a prolapse procedure, urodynamic investigation is recommende in these women prior to surgery[124].

The surgical anterior vaginal wall procedure seems to be effective to restore the symptom of incomplete emptying of the bladder (paper V) in line with another study[138].

According to the records, one-fifth of the women (n=54) had difficulty with defecation preoperatively in this study (Paper V). At the follow-up visit there were still 32 women with persisting symptoms of defecation difficulty. The surgical procedure was not effective in

restoring bowel symptoms, which is in line with other studies[84 103] and it was even reported that some women´s bowel symptoms get worse after the surgical procedure[103]. Regardless of the surgical technique there is a risk for failure of rectocele repair, for women with a preoperative history of constipation[124 204 205]. For women with bowels symptoms conservative treatment such as bulking agents and dietary changes is an alternative before surgery[103]. Furthermore, constipation might induce POP. It is possible that women with a symptomatic posterior vaginal wall prolapse and constipation after surgery may relieve symptoms related to stool trapping, but due to chronic constipation and straining have a higher risk of recurrence of POP[84 103].

Several studies show an increased risk of dyspareunia after performance of posterior colporraphy with a levator ani plication[84 103 140] and also deterioration of sexual function after surgery[206]. This was also shown in this study (Paper V). Surgical procedures for POP can result in shorter vaginal length and vaginal stenosis, and cause dyspareunia[103 107 139 207]. However, there were no significant differences reported in postoperative vaginal dimensions in women with and without dyspareunia[140]. Posterior colporrhapy seems to be most associated with dyspareunia[103], even if no plication of the levator muscle is done[103 140]. It has further been shown that the site-specific repair will improve results and decrease this risk[126 128], but levator placation was reported only in 1 of 15 women with postoperative dyspareunia[140].

The results of this study shed light on the modest long term anatomical cure rate after surgery for POP and also on the appearance of side-effects. The Manchester procedure has been the standard prolapse repair for decades and is still representative of prolapse repair in Sweden. During the last decade new procedures such as site-specific repair have been described and may improve the results after operation, relieve symptoms and restore anatomy. Care should be exercised in evaluating these new surgical procedures should be taken by thorough follow-up.

Evaluating the outcome of surgery for GSI and POP

The literature about the effectiveness of surgical treatment for POP and GSI has been sparse and limited concerning objective and subjective outcome in randomized long-term follow-up studies. Many reports include case series with small numbers of patients and follow-up time is often short[113]. Evaluation of symptom pre-and postoperatively is not standardized and

subjective outcome is seldom reported. There is a lack in knowledge about the correlation between anatomical support and symptom, and outcomes in terms of subjective and objective cure rate have not been studied.

In 1996, a working group from the American Urogynecology Society and the Society of Gynecologic Surgeons drew up a document on general principles whose implementation could be used to improve the quality of outcomes analysis in reconstructive gynaecological surgery[202]. There was a general consensus that standardized data should be collected on patients before and after surgery. The goal of surgery for POP is to effect changes in anatomical structure that provide patients with relief of symptom and avoidance of side effects.

In the last year several Norwegian departments have reported their data from surgery for stress incontinence to a National database, which generates reports for comparison of surgical procedures, department and surgeons[208]. In Sweden, a similar national database relating to surgery for GSI and POP is under development in the Urogynaecology Association (Ur-Arg) of the Swedish Society of Obstetrics and Gynaecology (SFOG).

General consideration

Poor pelvic floor support is commonly seen among parous women[8]. Symptoms vary and the most prevalent syndromes, urinary incontinence, POP and fecal incontinence, are a social and medical problem for many women. However, many women with decreased pelvic floor support have no symptoms at all.

Pelvic organ prolapse represents a spectrum of anatomical conditions ranging from asymptomatic posterior vaginal wall prolapse stage 1 (perineal descent after vaginal delivery) to complete prolapse (stage IV). The outcome of surgery does not only depend on the surgical skill, effort and technique when correcting the prolapse but also on the degree of loss of pelvic floor support.

The most important outcome of a surgical procedure for GSI or POP for the women is the relief of her symptom and improvement of her quality of life. Before surgery there should be a possibility to ask the patient to state and discuss her wish and for the surgeon to state her/his

opinion of the possibility for success of the surgical procedure[209]. Results in terms of objective and subjective outcomes are necessary to predict patient satisfaction.

Many lifestyle factors may have impact of the nature of urinary and faecal incontinence. Dietary and drinking habits may have importance for women with incontinence. Conservative treatment such as physiotherapy or lifestyle changes, are commonly recommended for women with POP or GSI with less symptoms and for those who wish to have more children, or those unwilling to undergo surgery[210]. Pelvic floor muscle excercises (PFM), with or without bio feed-back, electrical stimulation, medication, PFM with cones are all alternative to surgery for women with a mild degree of GSI or POP[210-212]. Mechanical treatment may be a possible treatment for older women with poor health and who do not want surgery[213]. However, more research of high methodological quality is required to further evaluate the effects of conservative therapies used to treat and prevent GSI[211] and there are no randomized trials of conservative management for POP[210].
There is need for well-designed randomized controlled trials in this area.[213]. The following comparisons wait to be done:

- The comparison of treatment with a mechanical device versus control/waiting list/no active treatment;
- The comparison of a mechanical treatment device versus surgery;
- The comparison of a mechanical treatment device versus physical interventions such as pelvic floor muscle training or lifestyle changes.

The care of women with pelvic organ dysfunction requires a multi-discipline co-operation between obstetrician, urogynecologist, urologist and colorectal specialist. These groups also have to enroll nurses and physiotherapists with special knowledge in the field.

To identify obstetric events which may deteriorate the pelvic floor it is necessary with prospective studies. Many women do have vaginal deliveries without pelvic floor damage. Is it possible to prevent vaginal lacerations with careful attention to the length of active second stage of labour? Can more careful surgical repair of lacerations (site specific repair of rectovaginal fascia) in connection to delivery prevent subsequent pelvic floor dysfunction? A multi center prospective study with examination of nullipara women and the pelvic floor anatomy according to POPQ in the beginning of their pregnancy and one year after their

labour would a study design. Thus, it may be possible to more in detail investigate possible putative risk factors at delivery for developing POP.

Pelvic floor disorders are a life-long, chronic condition with multifactorial genesis, as damage at childbirth, changing levels of hormone, connective tissue defects and congenital factors. Operative procedures may also contribute to pelvic support defects. Pelvic floor support follows a continuum from perfect to total absence. The lack of agreement about where to place the cutpoint between health and disease, and the weak scientific foundation for such agreement, complicate both the construction of measurement instruments and the interpretation of their results. The women will tend to define the condition in terms of symptoms, while the POPQ bases its classification purely on anatomic findings. Clinicians (and patients) would probably be most helped by indices that would point to an adverse outcome and if possible, to what kind of treatment that should be used. Therefore, prospective studies of the natural course in symptom-free women with stage I prolapse are clearly warranted. There are no published data on POP remission[124] and the influence of age is unclear.

Finally, as a urogynecologist, obstetrician and pelvic floor surgeon we have responsibility to understand, minimize, and possibly prevent, pelvic floor damage[214].

CONCLUSIONS

- Local symptoms such as sensation of something coming down in the vagina (vaginal bulge) and urinary symptoms such as voiding difficulties and urinary incontinence are symptoms linked to POP. Bowel symptoms are less associated with POP.

- Five questions manage to identify clinically significant prolapse with high specificity and reasonable sensitivity. Studies of the importance of asymptomatic stage 1 prolapse, often missed by our questionnaire, are clearly warranted in order to refine the borderline between normal and pathological lack of pelvic floor support. Although the sensitivity of the test was moderate, the specificity, and hence the ability to rule in cases, was satisfactory. The test is suitable for case finding in epidemiological studies.

- One out of twelve in the studied population has symptomatic POP. The increase in prevalence with age halts after childbearing age. It appears that parity is the strongest driving force in the development of symptomatic POP, but is not a necessary cause. Age *per se* – or factors linked to age – carries additional risk, particularly in middle-aged premenopausal women. After menopause, however, the prevalence appears to plateau. Urinary incontinence frequently co-occurs with POP**.**

- Manifestations of excessive stretching and tearing during labour are independent risk factors for symptomatic POP. Histories of any rupture (vaginal or anal sphincter tear) or episiotomy were associated with significantly increased odds of having this condition. Instrumental delivery, such as forceps and vacuum delivery did not seem to increase the risk, nor did length of labour or maternal age of delivery. Abdominal delivery appeared to be protective against symptomatic POP.

- Abdominal urethropexy-colposuspension is a useful method for treatment of genuine stress incontinence. The objective cure rate for correcting GSI was higher than the subjective cure rate (patient's satisfaction). Urge symptoms before operation was a negative prognostic factor for a good outcome in terms of subjective cure of incontinence, but had no impact on objective cure or satisfaction with the operation. Non-satisfied women at follow-up complained of urge incontinence.

- In evaluating the cure rate of pelvic floor surgery, not only the anatomical outcome should be studied but also the outcome in terms of side effects and/or symptoms as resolved, persistent or new onset. In this study an unsatisfactory anatomical outcome was not necessarily associated with symptoms. However, an unsatisfactory outcome concerning symptoms was associated with a history of complicated delivery and urinary incontinence. The modest cure rate after surgery may be due to the aggravation with time of the pelvic floor disorder, this confounding the results of surgery.

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Appendix I

Personnummer: …….

Vi är tacksamma om Du ger Dig tid att svara på dessa frågor om framfall.

Jag väntar på behandling av framfall ☐

Jag söker av andra orsaker ☐

Min ålder …….. år

1. Har Du en känsla av tryck eller tyngd mot underlivet?

   Ja ofta Ibland Någon gång Nej aldrig

2. Har Du en känsla av att något buktar ut ur slidan?

   Ja ofta Ibland Någon gång Nej aldrig

3. Händer det att Du har skavningsbesvär i underlivet?

   Ja ofta Ibland Någon gång Nej aldrig

4. Har någon talat om för Dig vid gynekologisk undersökning att Du har framfall?

   Ja Nej Vet ej

5. Hur ter sig Dina besvär under dagen?

   Sämre på morgonen Sämre på dagen Sämre på eftermiddagen Sämre till kvällen

6. Om Du anstränger Dig med t ex tunga lyft, blir Dina besvär:

   Oförändrade Bättre Sämre

7. Händer det att Du har svårt att tömma blåsan?

   Ja ofta Ibland Någon gång Nej aldrig

8. Händer det att Du har svårt att tömma tarmen?

   Ja ofta Ibland Någon gång Nej aldrig

9. Händer det att Du behöver lyfta främre slidväggen för att tömma blåsan?

   Ja ofta Ibland Någon gång Nej aldrig

10. Händer det att Du behöver hålla emot bakre slidväggen för att tömma tarmen?

    Ja ofta Ibland Någon gång Nej aldrig

11. Har Du besvär med att bli plötsligt kissnödig och har svårt att hinna fram till toaletten?

    Ja ofta Ibland Någon gång Nej aldrig

12. Har Du besvär av att läcka urin vid hosta, nysning, lyft etc?

    Ja ofta Ibland Någon gång Nej aldrig

13. Tror Du själv att Du har framfall?

    Ja Nej Vet ej

APPENDIX II ;FINAL QUESTIONNAIRE

KODNR.....

1. *Hur gammal är Du ?* ☐☐
2. *Har Du fött barn ?* ☐ i ☐
3. *Hur många ?* ☐☐

	Ja	*Nej*
4. *Har Du genomgått någon gynekologisk bukoperation?*	☐	☐
5. *Har Du genomgått någon framfallsoperation?*	☐	☐
6. *Har Du genomgått någon inkontinensoperation?*	☐	☐

	Ja ofta	*Ibland*	*Någon gång*	*Nej aldrig*
7. *Har Du besvär med att bli plötsligt kissnödig och har svårt att hinna fram till toaletten?*	☐	☐	☐	☐
8. *Kan Du läcka urin vid kroppslig ansträngning som hosta, nysning, gång i nedförsbacke eller hopp?*	☐	☐	☐	☐
9. *Har Du en känsla av att något buktar fram ur slidan?*	☐	☐	☐	☐
10. *Händer det Du har skavningsbesvär i underlivet?*	☐	☐	☐	☐
11. *Händer det att Du behöver lyfta upp främre slidväggen för att kunna kissa?*	☐	☐	☐	☐

”Om Du svarat ja på någon av frågorna 7-11, besvara även nedanstående fråga”.

	Oförändrade	*Bättre*	*Sämre*
12. *Om Du anstränger Dig med tex tunga lyft, blir Dina besvär:*			