To my daughter
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Abstract

Background: Pelvic organ prolapse (POP) is a relatively common condition. In Sweden, the overall estimated prevalence of POP in the female population is 31% and the prevalence of symptomatic prolapse is 8–15%. The prevalence of POP increases with age. The lifetime risk of undergoing pelvic floor surgery is estimated to 11%.

The aim of this thesis was to investigate outcomes of vaginal hysterectomy for treatment of prolapse; to study outcomes of cystocele repair surgery and patient satisfaction related to different anaesthesia methods; to explore women’s experiences of vaginal prolapse; and to investigate what is known regarding POP prior to surgery and healthcare-seeking behaviour.

Methods: In the Swedish National Quality Register for Gynaecological Surgery (Gynop-register), 941 women were identified who underwent vaginal hysterectomy for prolapse from 1997 to 2005 and 1,364 women were identified who underwent cystocele repair surgery from 2006 to 2009. In-depth interviews were performed with 14 women with vaginal prolapse. Interview data were analyzed with a qualitative content analysis. To investigate women’s knowledge about POP and healthcare-seeking behaviour, a questionnaire was developed, validated and distributed to women with planned surgery for POP. Women undergoing hysterectomy or incontinence surgery were used as reference groups.

Results: Severe complications after vaginal hysterectomy occurred in 3% of cases. Sexual activity was improved after vaginal hysterectomy, the number of women reported to have intercourse increased by 20% (p = 0.006). Subjective symptoms of urinary incontinence and overactive bladder were resolved in 50% of the women. De novo stress incontinence was reported by 11% of the women.

Use of local anaesthesia (LA) in reconstruction of cystocele showed advantage over other forms of anaesthesia. Length of hospital stay, duration of use of postoperative pain-killing drugs, and time to return to daily activity were shorter among women who underwent surgery with LA compared to other forms of anaesthesia. Patient satisfaction was not related to methods of anaesthesia.

In an interview study, the process from recognition of the symptoms to seeking healthcare was highlighted. Two categories, “obstacles” and “facilitators” to seeking health care, were identified. One of the obstacles was lack of information about POP in the public domain. The main facilitators were feeling sexually unattractive and impaired physical ability due to POP.

Some findings from the interview study were further explored in the questionnaire study. One out of five women with vaginal prolapse did not know that the symptoms were related to prolapse before consulting their physician. Over 30% of the women in the incontinence group were embarrassed to talk about incontinence, and they were unaware that it could be treated. The most frequent description of vaginal prolapse was vaginal bulging. Women in the prolapse group had significantly less access to information through brochures and public media than women in the incontinence group (p < 0.001).
Conclusion: Short-term follow-up after vaginal hysterectomy showed that sexual activity and urinary symptoms had improved. Cystocele surgery using LA showed no disadvantage compared to surgery using other anaesthesia methods. POP surgery can therefore be performed safely with LA. Information regarding prolapse should be easily accessible to improve the possibility for women of gaining knowledge and thereby overcoming obstacles to seeking medical advice. Healthcare professionals have a significant role to play in informing women about symptoms and available treatment options.
Svensk sammanfattning

**Bakgrund:** Framfall är ett vanligt förekommande tillstånd bland kvinnor. I Sverige uppskattas prevalensen av framfall i den kvinnliga befolkningen vara 31 % och prevalensen av symtomatiskt framfall 8-15%. Förekomsten av framfall ökar med stigande ålder. Risken för en kvinna att genomgå bäckenbottenkirurgi under sin livstid beräknas vara 11 %.

Syftet med denna avhandling var att studera resultat efter vaginal hysterektomi för behandling av framfall, att studera utfallet av cystoceleoperation relaterad till olika anestesiformer och att undersöka patientens tillförlitlighet i förhållande till olika anestesier. Vidare var syftet att utforska kvinnornas upplevelse av framfall och att undersöka deras kännedom om framfall och faktorer som påverkar att kvinnor söker sjukvård för sitt tillstånd.


**Resultat:** Efter vaginal hysterektomi tillstötte en svår komplikation hos 3 % av kvinnorna. Kvinnornas sexuella aktivitet har ökat efter vaginal hysterektomi. Antalet kvinnor som rapporterade att de hade samliv ökade med 20 % (p = 0,006) jämfört med preoperativt. Subjektivt upplevda symptomer av urininkontinens och överaktiv blåsa försvann hos 50 % av kvinnorna. Nytillkommen stressinkontinens rapporterades av 11 %.

Användning av lokalanestesi i cystoceleoperation visade fördelar jämfört med andra anestesiformer. Kvinnor som opererades i lokalanestesi hade i genomsnitt kortare vårdtid, behövde ta smärtstillande medicin kortare tid och återgick snabbare till daglig aktivitet jämfört med kvinnor som opererades i andra anestesiformer. Patientens tillförlitlighet var inte relaterad till användning av viss typ av anestesi vid operation.

Vid den intervju som genomfördes med kvinnor avseende deras upplevelse av framfall, belystes den process som började med igenkännande av symptom och som leddes fram till att kvinnorna sökte sjukvård. Två kategorier, ”hämmande” respektive ”främjande” faktorer för att söka sjukvård identifierades. En hämmande faktor för att söka sjukvård som beskrevs av kvinnorna var brist på information om framfall. Känsla av att vara sexuell oattraktiv och av nedsatt fysisk förmåga, till följd av framfall, var däremot faktorer som främjade kvinnorna att söka sjukvård.

Vissa fynd som vi fann i intervjustudien har vidare undersöks i en uppföljande enkätstudie. En av fem kvinnor med framfall visste inte att symptomen berodde på framfall. Över 30 % av kvinnor med urininkontinens skämdes att prata om sitt tillstånd och var omedveten om att till-
ståndet kunde behandlas. Den mest frekventa beskrivningen av framfall, bland de tre undersökta grupperna, var vaginal utbuktning. kvinnor med framfall hade mindre tillgång till information via broschyrer och media jämfört med kvinnor med urininkontinens (p < 0,001).

**Konklusion:** Korttidsuppföljning efter vaginal hysterektomi visade att sexuell aktivitet och urogenitalsymtom förbättrades. Cystoceleoperation i lokalaneesi visade inte på några nackdelar jämfört med operation i andra anestesiformer. Framfallsoperation kan därför med fördel genomföras i lokalaneesi. Information avseende framfall borde vara lättillgänglig så att kvinnor kan skaffa sig kunskap om tillståndet och övervinna hinder för att söka vård. Sjukvårdspersonal har en viktig roll för att informera patienterna om relaterade symtom och tillgängliga behandlingsalternativ.
# List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADL</td>
<td>Activity of daily life</td>
</tr>
<tr>
<td>ASA</td>
<td>The American Society of Anaesthesiologists Physical Status Classification System</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>CA</td>
<td>Content analysis</td>
</tr>
<tr>
<td>GA</td>
<td>General anaesthesia</td>
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<tr>
<td>Gynop-register</td>
<td>The Swedish National Quality Register for Gynaecological Surgery</td>
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<tr>
<td>HRT</td>
<td>Hormone replacement therapy</td>
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<tr>
<td>ICS</td>
<td>International Continence Society</td>
</tr>
<tr>
<td>LA</td>
<td>Local anaesthesia</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
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<tr>
<td>NBHW</td>
<td>National Board of Health and Welfare</td>
</tr>
<tr>
<td>PFD</td>
<td>Pelvic floor disorder</td>
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<tr>
<td>POP</td>
<td>Pelvic organ prolapse</td>
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<tr>
<td>POP-Q</td>
<td>Pelvic Organ Prolapse Quantification System</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>RA</td>
<td>Regional anaesthesia</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>SALAR</td>
<td>The Swedish Association of Local Authorities and Regions</td>
</tr>
<tr>
<td>SFOG</td>
<td>The Swedish Society of Obstetrics and Gynaecology</td>
</tr>
<tr>
<td>SUI</td>
<td>Stress urinary incontinence</td>
</tr>
<tr>
<td>UI</td>
<td>Urinary incontinence</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
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This thesis is based on the following papers, which will be referred to by their Roman numerals:


III Pakbaz M, Persson M, Löfgren M, Mogren I. ‘**A hidden disorder until the pieces fall into place’ – a qualitative study of vaginal prolapse.**’ BMC Women’s Health 2010, 10:18

IV Pakbaz M, Rolfsman E, Mogren I, Löfgren M. **Vaginal prolapse - Perceptions and health-care-seeking behaviour among women prior to gynecological surgery.** In manuscript

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**INTRODUCTION**

Vaginal prolapse is characterised by protrusion of the vaginal wall downward to the introitus. The term is synonymous with pelvic organ prolapse (POP), and the term prolapse used in this thesis refers to vaginal prolapse. One of the treatment options for uterovaginal prolapse is vaginal hysterectomy (1). Little is known about patient-perceived results of vaginal hysterectomy with prolapse as the indication. In the last decades, the use of local anaesthesia (LA) has been expanding in POP surgery. LA has been used to correct more advanced forms of vaginal prolapse (2-3). These studies have been performed by gynaecologists with great experience of prolapse surgery using LA. However, the degree of safety of performing prolapse surgery under LA in the routine healthcare setting is unknown. Furthermore, how patients perceive such care is also unknown. There have been few studies focusing on the effect of POP surgery from the point of view of the patient.

Most studies regarding POP have been related to surgical anatomical outcomes (4). Studies of women’s experiences and perceptions of vaginal prolapse are sparse. Thus, an interview study and a questionnaire study were conducted with women who had had vaginal prolapse.

The overall aim of the thesis was to investigate perception of vaginal prolapse, clinical outcomes, and the results of prolapse surgery from the patient’s point of view.
BACKGROUND

The International Continence Society (ICS) defined POP as descent of one or more vaginal segments: the anterior, the posterior, or the apex of the vagina (cervix/uterus) or vault after hysterectomy (5). This definition may include up to half of the female population (6-7). Pelvic floor disorder (PFD) includes urinary incontinence (UI), POP, and fecal incontinence. POP causes symptoms of the lower genital, urinary, and gastrointestinal tracts and negatively affects the quality of life of a patient, but rarely results in severe morbidity or mortality (8-9).

Prolapse surgery accounts for 20% of the patients on the waiting list for gynaecological surgery in the UK (10), and in Sweden approximately 7,000 surgeries due to POP are performed every year. The goals of surgery for POP should be relief of symptoms. Most studies evaluating outcomes of POP surgery have focused exclusively on anatomical success without considering the most important issue for the patient, which is symptom relief. There have been very few published studies on patient-perceived outcome after surgery for POP.

EPIDEMIOLOGY OF PELVIC ORGAN PROLAPSE

Most epidemiological studies on POP have been from selected materials such as clinical populations or surgical registers (11-13). Incidence and prevalence estimates based only on the rates of surgical procedures probably underestimate the magnitude of POP.

Loss of vaginal support is observed in 43–76% of women examined during routine gynaecological care, and 3–6% has descent of vaginal structures beyond the hymenal remnants (6, 14). In a cross-sectional study, prevalence of symptomatic POP was reported to be 3% (15). In Sweden, the prevalence of symptomatic POP has been estimated to range between 8.3% and 15% (16-17).

The lifetime risk of surgery because of POP by the age of 80 years has been estimated to be about 11% (13). An estimated 13–30% of patients will be in need of repeat surgery due to recurrence (13, 18).

ETIOLOGY AND RISK FACTORS FOR PELVIC ORGAN PROLAPSE

POP is multifactorial in its etiology (9, 19). The most prominent risk factor for development of POP is vaginal delivery (12, 20-23). Pelvic viscera are supported by the levator ani muscle and connective tissue attachments of the pelvic organs, the so-called endopelvic fascia (24). Defects in the levator ani muscle have been noted on MRI in 20% of primiparous women after a vaginal delivery, suggesting that it may contribute to development of POP (25-27). Furthermore, neuromuscular dysfunction that occurs during vaginal birth contributes to pelvic floor dysfunction (28-29). Other obstetric factors that have been associated with an increased risk of POP include forceps delivery and macrosomic infant (14, 30-31). Pregnancy itself has been suggested to be a risk factor for prolapse (32). Most cases of symptomatic prolapse appear a long time after vaginal delivery, and most women who have been pregnant do not have symptomatic prolapse (33).
Advancing age and increasing body mass index (BMI) have also been associated with POP (6, 13-14, 20-23, 30, 34-35). However, the possible correlation between prolapse and increased BMI is not confirmed in another study (31).

Furthermore, genetic factors (36-38) and ethnic differences (21, 39) have been suggested to play a part in the development of prolapse. African-American women show the lowest risk of developing prolapse compared to white women (21, 39), while Hispanic women have the highest risk of developing prolapse (14, 21). In addition, connective tissue disorders (40-41) and changes in the collagen metabolism (42) have been shown to be associated with an increased risk of POP.

The presence of oestrogen and progesterone receptors in the pelvic floor muscle and lower urinary tract have been demonstrated (43). Menopause is cited as a risk factor for POP, due to the loss of oestrogen production (44-45). However, there is limited evidence from randomised controlled trials concerning the use of oestrogen for prevention and management of POP (46).

Heavy lifting (36, 47-48) and repetitive straining in patients with chronic constipation (49-50) have been proposed to be risk factors for POP. Arya et al. showed that individuals with POP of stage II or greater had an increased risk of developing constipation (50). However, findings in some studies have shown a weak association between constipation and prolapse, and stage of prolapse does not correlate with bowel function (51-53). Likewise, an increasing prevalence of constipation with advancing age has been shown previously (54).

Previous hysterectomy has been identified as a risk factor for POP (12, 22, 55-57); however, development of symptomatic prolapse might occur many years after the hysterectomy (12-13, 22, 30, 58). The risk of prolapse following hysterectomy is 5.5 times greater in women undergoing hysterectomy for prolapse than in women undergoing hysterectomy for other reasons (12). In addition, the risk of undergoing POP surgery is 4 times greater in women with a vaginal hysterectomy (not for prolapse) than in non-hysterectomised women (56).

PELVIC ORGAN PROLAPSE QUANTIFICATION SYSTEM
In 1996, the International Continence Society (ICS) Standardisation Committee introduced a standard system of terminology for description of POP (5). The system is called the Pelvic Organ Prolapse Quantification System (POP-Q). The descent of the anterior, posterior wall and the apex of the vagina (cervix/vaginal cuff) are measured using the hymen as the point of reference while the patient is straining.

Five stages of vaginal prolapse are defined in the classification of POP-Q.
Stage 0: No prolapse.
Stage I: The most distal portion of the prolapse is > 1 cm above the level of the hymen.
Stage II: The most distal portion of the prolapse is ≤ 1 cm proximal or distal to the hymen.
Stage III: The most distal portion of the prolapse is > 1 cm below the hymen.
Stage IV: Complete eversion of the total length of the lower genital tract is demonstrated.

In a multi-centre observational study of 1,004 women aged 18–83 years, at routine gynaecological examination, 24% had stage 0 prolapse, 38% had stage I, 35% had stage II, and 2% had stage III prolapse according to POP-Q (14).
SYMPTOMS RELATED TO PELVIC ORGAN PROLAPSE

Symptoms related to pelvic organ prolapse are listed in Table 1.

Women with POP may have either one symptom, such as vaginal bulging or pressure, or a combination of symptoms from the bladder, the bowel, and/or the pelvic floor. The complex relationship between prolapse and symptoms has been investigated in several studies, and in general there are weak to moderate correlations between the degree of prolapse and the presence of specific symptoms related to the urinary tract, to the bowel, and to sexual function (6, 59-61).

Table 1. Symptoms associated with pelvic organ prolapse (Modified from Barber 2005).

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Differential diagnosis</th>
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<tbody>
<tr>
<td><strong>Local symptoms</strong></td>
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<tr>
<td>Sensation of vaginal bulging</td>
<td>Vaginal cyst</td>
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<tr>
<td>Vaginal pressure</td>
<td>Rectal prolapse</td>
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<tr>
<td>Sensation of heaviness in pelvis or vagina</td>
<td>Inguinal or femoral hernia</td>
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<td></td>
<td>Pelvic tumour</td>
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<tr>
<td><strong>Urinary symptoms</strong></td>
<td></td>
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<tr>
<td>Incontinence</td>
<td>Urethral sphincter deficiency</td>
</tr>
<tr>
<td>Urgency</td>
<td>Detrusor overactivity</td>
</tr>
<tr>
<td>Frequency</td>
<td>Urinary tract infection</td>
</tr>
<tr>
<td>Feeling of incomplete emptying</td>
<td></td>
</tr>
<tr>
<td>Manual reduction of prolapse to start voiding</td>
<td></td>
</tr>
<tr>
<td><strong>Bowel Symptoms</strong></td>
<td></td>
</tr>
<tr>
<td>Incontinence of flatus or liquid/solid stool</td>
<td>Anal sphincter disruption</td>
</tr>
<tr>
<td>Feeling of incomplete emptying</td>
<td>Rectal prolapse</td>
</tr>
<tr>
<td>Digital evacuation</td>
<td>Irritable bowel syndrome</td>
</tr>
<tr>
<td>Splinting vagina or perineum to complete defecation</td>
<td>Pelvic floor neuropathy</td>
</tr>
<tr>
<td><strong>Sexual symptoms</strong></td>
<td></td>
</tr>
<tr>
<td>Dysspareunia</td>
<td>Vaginal atrophy</td>
</tr>
<tr>
<td>Decreased arousal</td>
<td>Other sexual disorder</td>
</tr>
</tbody>
</table>

Local symptoms

The only symptom specific for prolapse acknowledged consistently by patients with severe prolapse is the presence of a vaginal bulge that is either visible or perceptible (6, 59-61). In studies with self-reported symptoms of POP, expressions such as ‘sensation of something falling out of the vagina’ have been used to describe vaginal prolapse (23, 62-64). Studies suggest that symptomatic prolapse of stage II or higher are more associated with local symptoms (35, 60-61, 64-65).

Several studies have indicated that pelvic floor symptoms increase when the edge of the prolapse extends beyond the hymen (35, 66-67). However, observation of pelvic organ support in women examined at a regular gynaecological examination revealed that only 2% had prolapse that reached the introitus (6). Furthermore, a recently published study has indicated that pelvic floor-related symptoms do not predict the anatomical location in women with mild to moderate prolapse (68), and symptoms such as vaginal heaviness and pressure appear to have a weak relationship with POP (6, 59, 61).
Urinary symptoms

Symptoms from the lower urinary tract can coexist with prolapse (55, 69-71). In a review article, the prevalence of stress urinary incontinence (SUI) in women with POP was reported to be 13–83% (72). Defects in the support of the anterior vaginal wall affect bladder and urethral function, with formation of cystocele and bladder neck hypermobility, contributing to SUI (73-74). Women with a mild degree of prolapse may have SUI (9, 71). In contrast, women in whom the prolapse extends beyond the hymen are less likely to report SUI due to mechanical obstruction of the urethra (6, 9, 59-61). These women are more likely to complain of obstructed voiding, of the need to reduce prolapse manually in order to urinate, and of urinary retention (9, 60). Women with advanced prolapse and no symptoms of urinary incontinence (UI) may reveal a UI during urodynamic investigation if their prolapse is reduced, so-called occult SUI (75). These women are at greater risk of developing SUI after surgery (76).

Post-void residual urine (> 100ml) is observed in 30% of women with stage III or stage IV prolapse (77). Urodynamic investigation of women with varying degrees of anterior vaginal prolapse has shown that women with grade III or IV cystocele have voiding dysfunction to a greater extent than women with a mild degree of prolapse (78). Symptoms of voiding dysfunction, particularly the need to splint to urinate, have been found to resolve postoperatively in the majority of patients who report the symptoms preoperatively (79).

The prevalence of urge/mixed UI in women with POP has ranged between 21%–73% in different studies (72). The relationship between the degree of prolapse and overactive bladder symptoms such as urgency and urge incontinence has been inconsistent in different studies (61, 78). Women with an advanced stage of cystocele are more likely to have overactive bladder symptoms and a urodynamic diagnosis of detrusor overactivity (52%) than women with a mild degree of cystocele (20%) (78). However, another study has demonstrated that advanced stages of prolapse are associated with a decline in the symptoms of urgency and urge incontinence (61).

Bowel symptoms

Bowel symptoms such as incomplete rectal emptying, the need for splinting and digiting in order to start or complete defecation, straining, fecal incontinence, and urgency are frequently symptoms reported by women with rectocele (49, 67, 80). However, there is a weak correlation between the severity of prolapse and bowel dysfunction (51, 59-61). Digitation to defecate is reported in 36% of women who have posterior wall prolapse and 25% of women with anterior and posterior wall prolapse of stage II or more (72). Some studies have indicated that most women with rectocele do not have bowel symptoms and that some women without prolapse may use digital pressure to accomplish bowel evacuation (49, 51, 81).

The prevalence of fecal incontinence in women with POP ranges between 7%–31% (72, 82-83). Vaginal prolapse and fecal incontinence share common risk factors, i.e. neuropathic and muscular injury to the pelvic floor during childbirth, and can also be an effect of ageing (33).

Sexual symptoms

The prevalence of sexual symptoms in women with POP (≥ stage II) ranges between 9%–57% (72). Women with POP are more likely to cite pelvic floor symptoms as a reason for sexual inactivity than women with other conditions (84-85). However, studies have suggested that in general,
women with POP have the same rate of sexual activity as women of the same age without POP (86). In women with POP, the most common reason for being sexually inactive is argued to be the result of ageing, of menopause, or to having no sexual desire (86-87).

The prevalence of sexual dysfunction in middle-aged women has been estimated to be about 8–17% (88). Interestingly, there is a high prevalence of pelvic floor dysfunction in this age group, but its effect on sexuality was not noted in that particular study. Observations based on case-control studies have demonstrated a lower frequency of intercourse in women with symptoms of UI/POP than in the controls (89-90). Furthermore, reduced sexual activity because of fear of urine leakage during intercourse was found to be more common in the group with UI/POP than in the controls (89). Handa et al. found that women with UI have more sexual problems than women with POP (90). The relationship between pelvic floor symptoms and sexual function was investigated in a case-control study, which demonstrated that women with symptomatic prolapse (stage III–IV) have reduced arousal and infrequent orgasm (91). Another interesting finding of this study was that age and menopause did not appear to be significant confounders.

In a review article, the prevalence of dyspareunia in women with POP of stage ≥ II was reported to range between 8%–69% (72). Most of the variation in the prevalence is due to inconsistent definitions and different outcome measures to assess dyspareunia (92). Dyspareunia has a multifactorial background and is a common symptom in older women; it is often due to vaginal dryness as a result of low oestrogen levels (93-95).

**TREATMENT**

The indication for treatment of POP is based on patients’ symptoms. According to published studies, when the leading edge of vaginal prolapse is beyond the hymenal remnants (some stage II and all stage III); women may have increased symptoms of prolapse (6, 35). The aim of the intervention should be improvement in subjective symptoms with minimal complications. Treatment options are expectancy, pessary use, or surgery. The choice of treatment options depends on the physician’s and the patient’s preferences.

**Expectancy**

Expectancy can be suitable in women who have a mild degree of prolapse and who report little or no bother from the disorder. Pelvic floor exercise is usually recommended during the expectancy period and is commonly used in the treatment of urinary and fecal incontinence (96-97). However, its roll in prevention and treatment of POP is uncertain (98). Results from one study have indicated that daily pelvic floor muscle training can slow progression of anterior prolapse in elderly women (99).

**Pessary**

The use of pessaries for POP is limited to women with symptoms of vaginal prolapse but who decline surgical intervention, who are awaiting surgery, who wish to have more children, or when surgery is not appropriate because of poor health. Most data on pessary use are limited to case reports of complications, and no randomised trials of pessary use in women with POP were identified in a Cochrane review (100).
Surgery
Women whose symptoms are not adequately relieved by conservative management or women who decline use of a pessary are candidates for surgery. POP can be managed surgically with either a reconstructive or an obliterative technique.

Obliterative surgery includes total colpocleisis or LeFort’s partial colpocleisis. These procedures are suitable for elderly, medically compromised women who are not sexually active. The aim of reconstructive surgery for POP is to restore the prolapsed vagina while preserving vaginal sexual function. The most preferred route for POP reconstructive surgery is vaginal, and as many as 80–90% of operations are performed in this way (11, 101). Prolapse can arise from an isolated segment of the vagina but several vaginal segments are often affected. As a result, reconstructive surgery involves a combination of repairs of anterior, apical, and/or posterior vaginal wall.

Recurrence of POP after surgery is not uncommon; an anatomical recurrence up to 40% has been observed at examination 5 years after surgery (102). Most reoperations due to relapse occur at the same anatomical site (60%), and a smaller proportion of reoperations (32%) occur at sites different to that of the previous surgery (18). Anterior wall repair is the most frequently performed operation, and a high rate of anatomical recurrence is well-known (19, 79, 103). Most studies have investigated reoperation rates based on anatomical recurrence without reporting POP-related symptoms (18).

The most frequently performed POP reconstructive surgery in Scandinavian countries has been the Manchester repair, which includes anterior and posterior colporrhaphy, cervix amputation, and perineorrhaphy (104). Several authors have reported the occurrence of dyspareunia and vaginal strictures after extensive prolapse surgery (105-106). Thus, avoidance of prophylactic repair of rectocele in asymptomatic women has been recommended (107). Crafoord et al. have shown the occurrence of a shift in treatment tradition to more selective compartmental repairs in Sweden (108).

Hysterectomy due to prolapse is usually performed by a vaginal approach (109). A recently published Swedish study has shown a five-fold increased rate of vaginal hysterectomy with prolapse as the indication (110). Simple vaginal hysterectomy is not effective in correcting the uterovaginal prolapse (111). Transvaginal apical suspension procedures include high uterosacral ligament suspension, iliococcygeus ligament fixation, McCall culdoplasty, and sacrospinous ligament suspension (112-113). Two frequent approaches for apical fixation include abdominal sacrocolpopexy, which suspend the upper vagina from the sacral promontory with synthetic material, and transvaginal sacrospinous ligament suspension, which put up the upper vagina to the ligament between the ischial spine and the sacrum (4). Comparison of these two procedures has revealed that abdominal sacrocolpopexy is associated with a lower degree of recurrent prolapse but greater morbidity and a longer surgery time than vaginal sacrospinous ligament fixation (4, 103, 114-115).

Because of the high anatomical recurrence rate in prolapse surgery, different kinds of biological and synthetic material, such as mesh, have been introduced in the last decade (4). Side effects associated with the use of mesh in the vagina include mesh erosion and dyspareunia (116-117). Thus, the use of mesh is recommended for selected patients only (116).
SURGERY FOR POP USING LOCAL ANAESTHESIA

The use of LA in prolapse surgery has been expanded in the last decade (2-3). However, there have been few studies comparing outcomes of POP surgery using different forms of anaesthesia and with long-term data on recurrence rate.

Over 800 consecutive gynaecological surgeries including endometrial resection, termination of pregnancy, and hysteroscopies have been performed under LA without sedation in an outpatient setting and are highly accepted by patients (118). Many such procedures are now commonly performed under LA. The first series of prolapse surgeries under LA in a group of elderly women (mean age 80 years) who were poor candidates for general anaesthesia showed the success of the procedures (119). Other studies have shown the feasibility of pelvic reconstructive surgery under LA (2, 120-123). A randomised trial comparing LA with sedation and general anaesthesia for the vaginal correction of POP showed that the total hospital costs were lower for the group that received local anaesthetic (124).

OUTCOME MEASURES

Outcome measures are tools used to determine the efficacy and side effects of a treatment. POP is a multi-dimensional phenomenon, and success of treatment is often difficult to define (125). However, most studies have focused on anatomical success without considering symptoms and the quality of life (QOL) of the patient. In most studies in this field, outcomes of surgery have been assessed using questionnaires evaluating the efficacy of treatment regarding symptoms, sexuality, and QOL (126). In Scandinavia, condition-specific questionnaires for POP and UI have been developed for identification of these disorders and for assessment of the subjective cure (64, 127).

Anatomical outcome versus subjective outcome

Due to the lack of standardised definitions for success of treatment following POP surgery, the National Institutes of Health (NIH) Workshop on Standardisation of Terminology for Pelvic Floor Disorders recommended the following definitions for treatment success: ‘optimal anatomical outcome’ (POP-Q stage 0) and ‘satisfactory anatomical outcome’ (POP-Q stage I) (128). However, 75% of women presenting for annual gynaecological examination without symptoms of POP will not meet the definition of ‘optimal anatomical outcome’ and almost 40% will not meet the definition of ‘satisfactory anatomical outcome’ (14).

Publications with the lowest success rates have defined success as more stringent anatomical outcomes while studies with the highest success rates have generally used subjective outcomes such as satisfaction and relief of symptoms of POP (115, 129).

Definitions of vaginal prolapse that include the absence of vaginal bulge symptoms have the strongest relationships with patients’ own assessment of improvement and treatment success, and are more clinically relevant (125).

PATIENTS’ KNOWLEDGE OF POP AND HEALTHCARE-SEEKING BEHAVIOUR

Several studies have investigated women’s attitudes to UI and healthcare-seeking behaviour (130-138); however, there have been few studies addressing POP and healthcare-seeking behaviour, and also patients’ knowledge about POP.
Earlier studies have indicated that women’s knowledge about pelvic floor disorders is of importance in seeking medical advice (130-131, 139). The level of knowledge of pelvic floor disorders and the impact of knowledge on healthcare-seeking behaviour was investigated in a multi-ethnic cohort of women (140). The findings indicated that there was greater patient awareness and education in white women than in non-white women, resulting in more frequent healthcare-seeking and reporting of symptoms. The knowledge barrier was found to be responsible for low care-seeking for UI in non-white (140) and Middle-Eastern women (141-142).

In Western countries, the hesitancy to seek medical advice regarding UI has been found to be lack of knowledge about causes and about the availability of treatment, the embarrassment of talking about incontinence, and the belief that incontinence is a normal part of ageing (130-134). In a cross-sectional survey of 2,310 women with UI, factors significantly associated with the decision to seek treatment were a duration of symptoms of more than 3 years, having a history of noticeable accidents, and impaired quality of life scores (135).

Studies of patients with chronic diseases such as arthritis and diabetes have shown that improvement in patient knowledge about the condition leads to improved compliance regarding treatment and can lead to behavioural change (143-144). As in the case of chronic diseases, improvements in patient knowledge about POP and UI may lead to an increased amount of healthcare-seeking behaviour in patients and, as a result, the physical and psychosocial morbidities associated with POP and UI may be reduced (139).

**PHYSICAL AND PSYCHOLOGICAL WELL-BEING RELATED TO POP**

Prolapse has a significant influence on the quality of a woman’s life (8, 145-146). Women who consider themselves as being symptomatic generally have a significantly higher stage of prolapse and poor QOL (145). Women’s well-being (body image, sexual function, pelvic floor related symptoms, QOL, depressive symptoms) are improved after both surgical and conservative treatment of POP (146-149). Jelovsek et al. found that women with advanced POP (of stages III or IV) are more likely to feel self-conscious and less likely to feel physically and sexually attractive than healthy controls (8). Age, race, parity, previous hysterectomy, and medical co-morbidities were not found to be significant confounders in that study.

**QUANTITATIVE STUDY DESIGN**

Most applied study designs include randomised controlled trials (RCT), case-control studies, and cohort and cross-sectional studies.

In RCT, comparable individuals are randomly assigned to a treatment group or a control group and are observed for a specific health-related outcome (150). Ethical aspects must be fully addressed in such studies. RCT studies are considered to be the golden standard of research design, most probably because they provide the most convincing evidence of relationships between exposure and effect (151). RCT study may be conducted in a single-blinded or a double-blinded fashion to account for the placebo effect and to reduce the introduction of bias due to patients’ and clinicians’ conceptions (151).

Case-control studies and cohort studies have opposite approaches. The cohort study begins with the identification of a population (cohort) with an exposure of interest and a non-exposed population for comparison. The investigators then follow the cohort over time and determine
the outcome in each group. In a case-control study, the researchers identify individuals with a disease or a health outcome of interest and a control or comparison group; exposures and risk factors are evaluated in these individuals. In a case-control study, a variety of exposures can be studied whereas in a cohort study, a variety of diseases can be studied (151). Cohort studies are usually prospective but they can also be retrospective.

In cross-sectional studies, subjects are sampled at a fixed point or period of time, and then the associations between the concurrent presence or absence of risk factors and diseases are investigated (151).

Table 2 lists the advantages and disadvantages of different study designs.

**Table 2.** Advantages and disadvantages of different study design (modified from Greenberg et al. and Fletcher et al.).

<table>
<thead>
<tr>
<th>Study design</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| RCT          | Best evidence study design  
              | No inclusion bias (using blinding)  
              | Comparable groups | Large sample size  
                  | Long term follow up (possible losses)  
                  | Expensive  
                  | Ethical concerns  
                  | Compliance |
| Case-control | Inexpensive  
              | Small sample  
              | May be completed rapidly  
              | Optimal for rare diseases  
              | Good for study of chronic diseases | Identifying controls may be difficult  
                  | More susceptible to selection bias  
                  | Difficult to establish temporal relationship between exposure and disease |
| Cohort       | Direct calculation of risk ratio  
              | Information on incidence of disease  
              | Able to study multiple exposure and multiple outcomes  
              | Minimizes bias | Time-consuming  
                  | May require large sample size  
                  | Expensive  
                  | Not efficient for study of rare diseases  
                  | Require long follow up period  
                  | Potential for loss to follow up |
| Cross-sectional | Usually use population-based samples  
                  | Use to assess the prevalence  
                  | Inexpensive  
                  | Useful for public health planning | Not strong at showing cause-effect relationship |

**QUALITATIVE RESEARCH IN UROGYNAECOLOGY**

Qualitative research is becoming more prominent in medical research (152). Most research in urogynaecology uses quantitative methods; however, editorials have advocated a greater role for qualitative research as a way to address both ‘clinical’ and ‘psychosocial’ issues (153-154). Despite the fact that qualitative research can offer valuable insights into urogynaecological problems, it has struggled to gain acceptance in this field (155).

**Qualitative research – an overview**

Qualitative research is an enquiry process for understanding of a social or human problem (156). The researcher analyses informants’ own words, and reports detailed viewpoints of informants.
Qualitative and quantitative research

Qualitative and quantitative methods are different tools in health research, and their applicability depends on the research question (152, 156). The qualitative and quantitative approaches complement each other in this kind of research.

Qualitative and quantitative methods have different research processes: inductive and deductive (152). The inductive approach in qualitative research refers to discovering something new, perhaps with the result that hypotheses can be generated, but the aim of research is not to prove them to be true or false. Quantitative research takes a deductive approach, meaning that it tests a hypothesis. This method is suitable for measuring a certain condition or well-described phenomenon in a population, and when the research field has already been explored and the researcher wants to verify a hypothesis (152). Qualitative methods are suitable when the research field is unexplored, or when a flexible approach is required for exploring the unexpected, or when it is desirable to look into an issue in depth (152). A qualitative study may produce ideas, theories, and hypotheses that can be tested in a quantitative study (156).

Some central concepts in qualitative research projects are natural setting, emergent design, saturation, and purposive sampling (152). Research can be undertaken in a variety of settings (the specific places where information is gathered). Qualitative researchers are especially likely to engage in natural settings because they are interested in the context of people’s lives and experiences (158). A design that unfolds in the course of a qualitative study as the researcher makes ongoing design decisions, reflecting what has already been learned, is called emergent design and is a way of enhancing the quality of the research (152, 158). In qualitative methods, data are commonly collected until a level of saturation has been achieved, meaning that no further substantial information can be obtained by further recruitment of informants (152). Sampling in qualitative research focuses on purposive sampling, i.e. a striving for maximum variation in, for example, background characteristics of the informants included in a study (159). Quantitative research focuses on probability sampling; that is, everyone in the study population has an equal chance of being selected (152).

One inevitable issue in qualitative research is the interaction between the researcher and the participants (152). The researcher’s interest can influence the research process. In quantitative research, certain precautions are taken to eliminate subjectivity (159). However, the researcher is always a subject in qualitative research (152). Taking advantage of the researcher’s earlier experiences to enhance the quality of data is stressed (160), and it is important that researcher’s pre-understanding and expectations should be debated openly (152).
Qualitative content analysis

Content analysis (CA) is analysis of themes and patterns that emerge in the narrative content (158), and it deals with both manifest and latent content in a text (161). The manifest content refers to what the text says and the latent content refers to what the text implies (161). Focus in CA is the subject and the context and emphasize differences between and similarities within codes and categories (161). Three different approaches have been identified in qualitative CA (162): conventional CA, directed CA, and summative CA. Conventional CA is usually appropriate when existing research literature on a phenomenon of interest is restricted and coding categories gain from the textual data (162). Directed CA is appropriate when existing research literature on a phenomenon is incomplete and would benefit from further description. This approach is a deductive one, and the existing theory is a guide for the coding process (162). Summative CA starts with identification and quantification of certain words or content in a text, followed by interpretation of the underlying context.

Trustworthiness in qualitative research

In qualitative research the concepts credibility, dependability, transferability and confirmability are used to define the various aspects of trustworthiness (159, 161).

The credibility of findings in qualitative research depends on the collection of data as well as on the analysis of data, i.e. how well the data and the process of analysis address the original intention (159). Choosing participants with a range of experiences increases the possibility of approaching the research question from different angles (161). A well-structured methodology with stepwise procedures in the content analysis enhances the credibility in the analytical phase. Another aspect of the credibility of research findings is the degree of agreement between co-researchers and participants (161). The value of dialogue between co-researchers and of seeking agreement has been defended in qualitative research (161). The intention is to determine whether co-researchers agree with the way the data have been labelled (161).

Dependability is another aspect of trustworthiness, meaning that the study must adjust to new forms of input obtained during the study period (161, 163). Based on the new data obtained, the alterations in the researcher’s decisions during the analysis process can be discussed by open dialogue to judge the consistency of the content over time (161).

Transferability refers to the extent to which the results of a study can be transferred to other settings (159, 161). By giving a clear description of informants’ characteristics, culture, and context, readers can be provided with enough information to decide whether the findings are transferable to another context (161).

Confirmability in qualitative research implies that the neutrality of a research project is focused on the data and the interpretation of the data, instead of on the researcher as a subject (161). Describing the analytical procedure and giving quotations from the transcripts is a way of verifying that the findings are derived from the data and that they are not a result of the researcher’s preconceived ideas or assumptions (159, 163).

THE HEALTHCARE SYSTEM IN SWEDEN

Sweden has 9 million inhabitants and is the third largest country in Western Europe in terms of area. Sweden has Europe’s proportionally largest elderly population, with over 5% of the
population in the age stratum of 80 years or older. Most of the healthcare services in Sweden are public, and everyone has an equal right to such services (164). In Sweden, each inhabitant has a unique personal identification number. The database of the Swedish Inpatient Register at the National Board of Health and Welfare (NBHW) contains discharge data according to the International Classification of Diseases (ICD-10) codes for specific disease diagnoses, including surgical procedures for all admissions at public hospitals (165).

HEALTHCARE QUALITY REGISTERS IN SWEDEN

History
A system of national quality registers has been established in the Swedish health and medical services in the last decades. The Swedish Association of Local Authorities and Regions (SALAR) and the NBHW have collaborated to support the development and use of National Quality Registers (166). This collaboration is looked after by the Executive Committee for National Quality Registers. This committee also includes representatives from the Swedish Society of Medicine and the Swedish Society of Nursing. Until 2007, the quality registers were under the auspices of the NBHW. From 2007, SALAR has taken on the primary responsibility for the development and financing of the registers.

There are about 70 health quality registers in Sweden. Development of the registers has been done by representatives of the professional groups that use them. National Quality Registers contain data on patient diagnosis, treatment interventions, and treatment outcomes. These are monitored annually and approved for financial support by the Executive Committee. Many registers cross-match the register data with those in the national health databases, for example, the Cause of Death register, to enhance their analytical capacity further.

Aim of the quality registers
The main aim of health quality registers in Sweden is quality control of healthcare and improvement of the quality of healthcare in the Swedish health services. The secondary aim of the registers is to be used for research on health and medical services in accordance with SFS 2008:335, capture 7, §5 (167).

Data from healthcare quality registers make it possible to follow up and develop medical healthcare in Sweden. One of the purposes of the national quality registers is to provide benchmarking data, i.e. to enable individual hospitals to measure the treatment results regarding certain conditions and to compare them with the Swedish national average results, and with corresponding results from other Swedish hospitals (164). Large quantities of data that are collected annually in the national healthcare quality register make it possible to detect problems or complications rapidly. Register data can be used for improvement of the quality of health services. The uses of healthcare quality registers have become wider since some registers have started to include patient-perceived quality of life in addition to the medical data.

The Swedish National Quality Register for Gynaecological Surgery (Gynop-register)
The Gynop-register was established in 1997 by jointly agreement between the Swedish Society of Obstetrics and Gynaecology (SFOG) and the NBHW with a view to quality control of en-
doscopic surgery (168). The register has been expanded since then and currently includes six sections covering different surgical areas of gynaecology. Initially, hysterectomy due to benign conditions, ovarian surgery, and intrauterine surgery (endometrial ablation) were included in the Gynop-register. Since 2006, malignant gynaecological surgery, incontinence surgery, and POP surgery have also been included in the register. Data in the Gynop-register are cross-matched with the Cause of Death Register, the register of the total population, and the Inpatient Register to enhance the validity and analytical capacity of the data (168).

The Board of the Gynop-register consists of one manager, six gynaecologists (each one of whom is responsible for a specific section in the register), one member of SFOG, one chief representative from one gynaecology clinic, and one Board secretary. Västerbotten County Council is the authority responsible for the Gynop-register. The main financiers are SALAR and the participating clinics.

**Inclusion of patients in the Gynop-register**

Patients with a planned operation are included in the register. In order to avoid selection bias for registration of patients in the Gynop-register, inclusion of the patients is done by the operations-planner nurse or secretary. In accordance with the regulations of the management of National Healthcare Quality Registers, patients receive written information about the register and they have an opportunity to decline participation (167). All data extracted from the register for analysis is encoded, and it is not possible to identify any of the patients. Patients have the right to ask for their register record once a year.

During the period 2007 to 2010, the board of the Gynop-register offered an inspection visit to all gynaecological clinics, and in total 15 clinics (belonging to both university and county hospitals) accepted the offer and inspections were performed thereafter. The aim of the visit was to determine the proportion of patients with a planned surgery included in the register. The number of gynaecological surgeries performed (according to the clinic’s surgical register) was compared to the number of surgeries registered in the Gynop-register at the clinic under inspection. According to the results of the inspections at the clinics, the mean proportion of patients included in the register was found to be 96% of eligible patients.

**Data collection procedures in the Gynop-register**

Data in the register are collected through patient questionnaires and forms completed by surgeons (169). Until 2005 patients received two follow-up questionnaires, two months and six months after surgery. Since 2006 the one year follow-up questionnaire has replaced the six-month follow-up questionnaire. Table 3 shows the data collection procedure in the Gynop-register. The questionnaires have been validated through collaboration with the Department of Applied Educational Science at Umeå University, Sweden. Validated questionnaires for identification of symptoms related to POP and UI are included in the preoperative and follow-up questionnaire (64, 127).
Table 3. Data collection procedure in the Gynop-register.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Collection time of the questionnaire</th>
<th>Questionnaire data content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative patient questionnaire</td>
<td>At decision for surgery</td>
<td>Sociodemographic data, health status, and medical assessment of patient’s health data and symptoms reported by the patients</td>
</tr>
<tr>
<td>Preoperative form (Gynecologist)</td>
<td>At decision for surgery</td>
<td>History; physical and gynecological examinations</td>
</tr>
<tr>
<td>Operation form (Gynecologist)</td>
<td>Directly after surgery</td>
<td>Surgery data</td>
</tr>
<tr>
<td>Postoperative form (Gynecologist)</td>
<td>After discharge</td>
<td>Course of events during hospital stay</td>
</tr>
<tr>
<td>Two-month follow-up questionnaire</td>
<td>Sent 6 weeks after surgery.</td>
<td>General and medical follow-up questions, well-being and surgery-related complications, recovery, and improvement; gynecologist assesses patients' answers</td>
</tr>
<tr>
<td>One year follow-up questionnaire</td>
<td>Sent 1 year after surgery.</td>
<td>Identical questions as in preoperative for urinary symptoms, local symptom related to prolapse and sexual activity. Ratings of satisfaction; gynecologist assesses patients' answers</td>
</tr>
</tbody>
</table>

The Urogynaecology Association (Uro-Arg) within SFOG is responsible for part of the content of the patient questionnaires and surgeons’ forms. Since 2008, patients have been invited to answer the questionnaire through the Internet. Patients who have an e-mail address can receive an e-mail giving the password to a web link where they can answer the questionnaire. Patients who do not have an e-mail address, or whose e-mail address is not requested, also have an opportunity to answer the questionnaire on-line through specific information given in the questionnaire that is sent by post. However, patients who receive a questionnaire on paper rarely answer it on-line (< 5%). The overall response rate for the patient questionnaire is over 90% and the surgeons’ form is completed in 90% of cases.

Coverage of the Gynop-register

Of 53 gynaecology clinics in Sweden, 43 (81%) currently participate in the Gynop-register. Of the participating clinics, 37 (86%) clinics register data on POP surgery in the register. In order to investigate the coherence between the number of patients who were admitted to hospitals for POP surgery and included in the Gynop-register and the number of patients included in the Swedish Inpatient Register (165), a comparison was made between these two registers. In the Swedish Inpatient Register, 5,017 patients were identified who underwent POP surgery during 2009 and the corresponding figure in the Gynop-register was 2,571 patients. Table 4 gives the coverage of the Gynop-register in the different counties in Sweden, and the number of patients who underwent POP surgery during 2009 in each county. One can conclude that the Gynop-register has good coverage of clinics performing surgery for POP in relation to all clinics performing prolapse surgery in Sweden. The Gynop-register covers 51% of the patients undergoing surgery for POP in the inpatient care.
Table 4. Number of patients who underwent prolapse surgery during 2009 according to the Swedish Inpatient Register and the Gynop-register.

<table>
<thead>
<tr>
<th>County</th>
<th>A (n = 5017)</th>
<th>B (n = 2571)</th>
<th>Proportion B/A (%)</th>
<th>Proportion of clinics participating in the prolapse section of the Gynop-register (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stockholm</td>
<td>928</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Uppsala</td>
<td>182</td>
<td>99</td>
<td>54</td>
<td>100*</td>
</tr>
<tr>
<td>Södermanland</td>
<td>146</td>
<td>6</td>
<td>4</td>
<td>33</td>
</tr>
<tr>
<td>Östergötland</td>
<td>112</td>
<td>143</td>
<td>127</td>
<td>100</td>
</tr>
<tr>
<td>Jönköping</td>
<td>181</td>
<td>195</td>
<td>107</td>
<td>100</td>
</tr>
<tr>
<td>Kronoberg</td>
<td>145</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Kalmar</td>
<td>175</td>
<td>183</td>
<td>104</td>
<td>100</td>
</tr>
<tr>
<td>Gotland</td>
<td>34</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Blekinge</td>
<td>122</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Skåne</td>
<td>596</td>
<td>141</td>
<td>24</td>
<td>50**</td>
</tr>
<tr>
<td>Halland</td>
<td>245</td>
<td>84</td>
<td>34</td>
<td>50**</td>
</tr>
<tr>
<td>Västra Götaland</td>
<td>835</td>
<td>745</td>
<td>89</td>
<td>70**</td>
</tr>
<tr>
<td>Värmland</td>
<td>196</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Örebro</td>
<td>142</td>
<td>135</td>
<td>95</td>
<td>100</td>
</tr>
<tr>
<td>Västmanland</td>
<td>186</td>
<td>178</td>
<td>96</td>
<td>100</td>
</tr>
<tr>
<td>Dalarna</td>
<td>196</td>
<td>168</td>
<td>86</td>
<td>100</td>
</tr>
<tr>
<td>Gävleborg</td>
<td>163</td>
<td>161</td>
<td>99</td>
<td>100</td>
</tr>
<tr>
<td>Västernorrland</td>
<td>91</td>
<td>65</td>
<td>71</td>
<td>66**</td>
</tr>
<tr>
<td>Jämtland</td>
<td>65</td>
<td>64</td>
<td>98</td>
<td>100</td>
</tr>
<tr>
<td>Västerbotten</td>
<td>104</td>
<td>105</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Norrbotten</td>
<td>173</td>
<td>99</td>
<td>57</td>
<td>66**</td>
</tr>
</tbody>
</table>

A: Number of patients in the Swedish Inpatient Register, B: Number of patients in the Gynop-register.
*Registration started in 2009.
**Inspections were performed by the Board of the Gynop-register. Among clinics being inspected a mean registration rate of 96% (range 80–100%) for registration of the data has been found.
Aims

The aims of the study were:

1. To investigate complications and patient-perceived outcomes of vaginal hysterectomy for correction of uterovaginal prolapse (Paper I).
2. To investigate outcomes of cystocele repair surgery and patient satisfaction related to different forms of anaesthesia (Paper II).
3. To elucidate women’s experiences of vaginal prolapse and its effect on their daily lives (Paper III).
4. To investigate perception of vaginal prolapse and healthcare-seeking behaviour among women prior to gynaecological surgery (Paper IV).
SUBJECTS AND METHODS

PAPER I

A cross-sectional, retrospective study was performed and data on subjects in the hysterectomy section of the Gynop-register were included in the study. Subjects with uterovaginal prolapse who had undergone vaginal hysterectomy from January 1997 to August 2005 were included. The exclusion criterion was surgical correction other than vaginal hysterectomy. In total, 941 women who had undergone vaginal hysterectomy because of uterovaginal prolapse were identified. Data analysis was based on completed responses from the pre- and postoperative surgeons’ forms and patient questionnaires (169). A two-month follow-up questionnaire was sent to 827 women, and 791 responded (95.5%). A six-month follow-up questionnaire was sent to 748 women, and 682 responded (91%). Twenty-two women were assessed by the responsible surgeons to be unable to respond to the follow-up questionnaire due to language difficulties, advanced age, or mental disorders, and a further 28 women refused to respond to the questionnaire (Figure 1).

Figure 1. Selection of subjects eligible for the study

Data on patient characteristics, health status, and reported symptoms were retrieved from the preoperative patient questionnaire. Data on surgery and complications during surgery were collected from the surgeons’ operative questionnaire. Data on course of events during hospital stay were extracted from the surgeons’ form that was completed postoperatively. Data on patient-reported complications (unexpected events) were collected from the two-month follow-up questionnaire. In the preoperative and the six-month postoperative patient questionnaires, questions relating to symptoms of vaginal protrusion/ vaginal heaviness and urinary problems were requested in order to evaluate the effect of surgery. The questions regarding urinary problems and incontinence contained ‘yes’ or ‘no’ answers. Patients’ responses enabled us to identify four groups of urinary problems: (1) incontinence without urgency, interpreted as being stress incontinence; (2) urgency
without incontinence, interpreted as being urgency problems; (3) urgency and incontinence, interpreted as being urgency incontinence; or (4) no reported urinary symptoms. Sexual activity was reported by answering the question ‘have you had coitus in the past three months?’ Symptoms regarding dyspareunia, sensation of vaginal heaviness were reported in a visual analogue scale (VAS) of five grades, both preoperatively and postoperatively. The scale measured from 0 to 50 mm with 0 corresponding to complete absence of symptoms and 50 corresponding to unbearable symptoms.

**NON-RESPONSE ANALYSIS (PAPER I)**

Medical records were retrieved for 36 women for whom a follow-up questionnaire was sent but no answer was recorded in the register. One subject had been exposed to a severe complication (intra-abdominal haematoma) before discharge from the hospital, which was subject to reoperation and was reported in the postoperative discharge form by the surgeon. Two complications considered as being mild (urinary tract infection and vaginal vault haematoma with spontaneous drainage) were also noted. Of the patients without discharge data (n = 22), 17 had reported a recovery without complications in the two-month follow-up questionnaire. The medical files did not reveal any complications for the remaining five patients. We did not find any complications during their hospital stay that were reported by the patients but not registered by the surgeons.

**PAPER II**

A cross-sectional, retrospective study was performed. Women who underwent surgery for cystocele (without use of mesh) and who were registered in the prolapse section of the Gynop-register were included in the study. The study period was from January 2006 to June 2009. During this period, 33 gynaecological clinics registered POP surgery in the Gynop-register. Figure 2 presents the catchment area for the participating clinics during the study period.

We found 1,739 subjects who had undergone cystocele repair surgery during the study period. However, the form of anaesthetic method used was not registered in all cases. To eliminate selection bias regarding registration of anaesthetic methods, clinics that had more than 40% missing data regarding registration of the currently used anaesthetic method were excluded from the study (representing 175 operations in four hospitals). The cut-off point of 40% was chosen because it was found to be the largest gap between hospitals regarding missing registration of anaesthesia data. Of 1,564 eligible women, 200 were excluded from the

*Figure 2. The coloured area represents the catchment area for the participating clinics during the study period.*
study because of lack of information on the anaesthetic method used. Subsequently, 1,364 women were identified with complete information.

Data from forms completed by the surgeon perioperatively and postoperatively and patient questionnaires were analysed. The following variables were extracted from the preoperative and operative surgeons’ form: grade of physical status of the patient (according to the American Society of Anaesthesiologists physical status classification system; ASA); expected operative condition; recurrence of cystocele; anaesthesia method; estimated operative time and blood loss; and perioperative complications. The following variables were extracted from the postoperative surgeons’ form: length of hospital stay; use of in-dwelling catheter; and complications during the hospital stay. From the preoperative patient questionnaire, data on patient characteristics, symptoms of UI, and general health were collected. The variables retrieved from the two-month follow-up questionnaire were: patient-reported complications for which the patient sought medical care; symptoms of UI; patient’s self-estimated duration of time to return to daily activities (ADL); number of days using pain-killer medication (pills); the patient’s estimated length of hospital stay; the patient’s condition after surgery; and whether the patient would recommend this surgery to someone else. Patients’ statements on whether they would recommend the surgery to other patients (yes, no) and their condition after surgery (improved, not improved) enabled us to define their degree of satisfaction with the procedure (satisfied, dissatisfied). Patients were considered satisfied if they could recommend the surgery to others and if their condition had improved after surgery.

In total, 1,194 subjects received a follow-up questionnaire two months after surgery and 1,091 (91%) responded. Of the 273 women who had not responded to this follow-up questionnaire, 170 had undergone surgery less than 2 months previously and thus had not had any opportunity to answer the questionnaire.

When paper II was published, we did not have the one-year follow-up data on results after surgery, in which local symptoms, e.g. sense of vaginal bulging, were asked about and stated by the subjects. Since the one-year follow-up data are now available, we chose to present the data concerning local symptoms related to POP. The variable ‘do you feel something bulge from the vagina?’ was extracted from the follow-up questionnaire. This question was answered by patients in both the preoperative and the follow-up questionnaire one year after surgery. The response options ‘never’ and ‘almost never’ were considered to be ‘no’, meaning that they did not feel a vaginal bulge. The response options ‘once to three times per month’ and ‘once to three times per week’ and ‘daily’ were considered to be ‘yes’, meaning that they felt a vaginal bulge.

Univariate and multivariate regression analysis was conducted to investigate the characteristics that were significantly associated with patient satisfaction.

PAPER III
A qualitative study was conducted using content analysis. An interview guide was developed using open-ended questions addressing different topic areas, based on the scientific literature and the clinical experiences of the research group in this medical field.

The informants were women with POP of stage II or more according to the POP-Q classification system (5) and who were on the waiting list for primary surgery at a hospital in northern Sweden. Initially, eight women were approached. They were contacted by telephone by the author and informed about the aims of the study, and were asked to participate in an interview. Sub-
subsequently, an information letter was sent to the informants who had said that they were willing to participate in the study, and the information letter also emphasised that participation in the study was voluntary. Recruitment of the informants was according to ‘purposive sampling’, i.e., aiming at the greatest variation in characteristics such as age, occupation, parity, BMI, and marital status in order to capture extensive narratives from the informants. Verbal informed consent was obtained from all the informants before the interview was conducted. The interviews were recorded on tape and transcribed verbatim.

After eight interviews with parallel analysis, a revision of the interview guide was made as part of the emergent design, and four additional informants were recruited to the study. Data were collected until ‘saturation’ was achieved, that is, when no significant new information was obtained by conducting further interviews. Emergent design and saturation of the collected data was inspired of Grounded theory. After 12 interviews, the saturation of data related to the study question had probably been achieved; however, two final interviews were conducted to ensure that no substantially new experiences would come to light. The data were analysed according to manifest and latent content analysis, which is a stepwise process (161). In the first step, the text was read thoroughly to obtain a sense of the whole and to identify the content. Secondly, the text was divided into units of meaning to make the text shorter, while keeping its core message. At the third step, the meaning units were condensed and labelled with codes. Fourthly, the various codes were compared on the basis of similarities and differences and sorted into two categories and 11 subcategories. The final step of the analysis was to identify a theme. To validate the findings, the findings at the different steps of the analysis were discussed within the research group until consensus was achieved.

My pre-understanding
I have studied medicine in Sweden and I am a specialist in obstetrics and gynaecology with clinical training in Sweden. My main field is urogynaecology which includes pelvic floor-related conditions, e.g. POP and female urinary problems. I have worked in this clinical field since 2003. I participated in an academic course on content analysis in 2009.

PAPER IV
A prospective, cross-sectional questionnaire study was conducted. The exclusion criterion was surgery for recurrence of POP. Women with planned surgery for POP were included (n = 214). Women with planned surgery for hysterectomy (benign indication; n = 186) or incontinence (n = 161) were chosen as reference groups. The study period was from March to June 2010. Based on the findings in paper III, a questionnaire was developed and validated (Appendix 1). The questionnaire consisted of open-ended and multiple-choice questions in which the participants could choose one or more options. Participants had the opportunity to write an answer of their own in a free space if none of the available options were suitable. The questionnaire included items requesting the women’s description of POP and its causes, healthcare-seeking behaviour, and sources of information on their own condition. In addition, information on former education and duration of symptoms was provided by the patients on the questionnaire form. If the duration of symptoms was reported to be more than one year, the participants were requested to describe the reasons for not seeking health care earlier and their current reasons for seeking
help, in two multiple-choice questions. The questionnaire also contained questions regarding the information women received from the gynaecologist concerning effects of surgery on urinary symptoms, bowel symptoms, and sexuality. However, these data from the questionnaire are not presented in this thesis. All multiple-choice questions included the open response option “other reasons”, whereby participants had the opportunity to write an answer of their own, either alone or in conjunction with marking (an) other option(s). Comments were coded as: (i) marking an available option(s) and writing the same option as well; (ii) not marking an available option, but writing the same or a corresponding alternative instead in own words; (iii) marking “other reason” and/or producing an answer that was beyond the available options. In case of the second alternative, the available option was registered. The pre-existing options covered 91–99% of the answers produced.

Description of vaginal prolapse was investigated by two open-ended questions: ‘what is vaginal prolapse?’ and ‘what can cause vaginal prolapse?’ Responses to the open-ended questions were coded and similar codes were classified in the same category.

We used the Gynop-register as a tool for the data collection since 70% (n = 37) of the gynaecology clinics in Sweden use the register for POP surgery, and 68% (n = 25) of the participating clinics use web-based questionnaires (WBQ) in addition to paper questionnaires for data collection. The questionnaire was distributed along with the preoperative questionnaire (on-line or paper). Eligible participants received written information about the aim of the study, and they were informed that the questionnaire was for research purposes and that participation was voluntarily. They were also informed that the healthcare providers would not have access to the content of the questionnaire.

Eligible participants in the study were women who reported an e-mail address and responded a WBQ (n = 561). However, seven hospitals distributed the questionnaire in the paper format to women who were willing to participate but who did not have an e-mail address (n = 79). The hospitals were chosen based on their different geographic locations and they included both university and county hospitals. Women who received a WBQ answered our questionnaire in 95% of cases.

STATISTICAL METHODS
All statistical analysis in papers I, II, and IV were performed using the SPSS software package version 11.5, 16, or 18.

Paper I and IV
Categorical variables were analysed by Pearson’s chi-squared test and parametric data were analysed by \( t \)-test. Holm’s corrected Bonferroni method was applied to control for multiple testing. A \( p \)-value less than 0.05 was considered significant.

Paper II
For comparison between groups, categorical variables were analysed using Pearson’s chi-squared test, and parametric data were analysed using \( t \)-test. For continuous variables with a skewed distribution, the Kruskal-Wallis and Mann-Whitney tests were used. ANOVA was used to analyse normally distributed variables. Holm’s corrected Bonferroni method was used to correct for
multiple testing. Univariate and stepwise multivariate logistic regression analyses were performed to investigate the association between different variables and increased patient satisfaction. Continuous variables such as age and hospitals were dichotomised. Age was dichotomised at 50 years (approximate menopausal age). The variable hospital was dichotomised into two categories constituting hospitals either using LA in less than 50% at cystocele operations, or more than or equal to 50% (50% was the largest gap between the hospitals for use of LA). For the univariate analysis, the crude odds ratios (OR) with their corresponding 95% confidence intervals (CI) were calculated. All statistically significant variables (p < 0.05) in the univariate analysis were tested by performing multivariate logistic regression analysis. Significant variables were entered in a stepwise manner. A linear regression analysis was conducted, weighted by number of patients (n = 1,364) with proportion of use of LA per hospital as independent variable and proportion of postoperatively inserted urinary catheter and length of hospital stay as dependent variables.

ETHICS
All studies were approved by the Regional Ethical Review Board in Umeå, Sweden (Dnr. 08-076, Dnr. 2010-31-32).

The main advantage of using register data is that they already exist. Thus, the time spent on data collection for studies is shorter than the time needed for primary data collection (170). Sweden has a long tradition of healthcare quality registers and population-based registers. The Cancer Register was established in 1958 and the Gynop-register started to collect data in 1997. The legislation of using register data for research purposes has become more elaborate in the last decade due to issues regarding integrity of the individual (167). A definite requirement is that subjects should not be identifiable throughout the research process.

Patients with a planned surgery were included in the Gynop-register. In accordance with the regulations of the management of National Health Quality Registers, patients had received written information on the register and they had had an opportunity to decline participation in the register. All data extracted from the register for analysis were coded and individual patients could not be identified. Information on individual patients is protected according to 13§ of the Swedish Personal Particulars Law (PuL). Patients have the right to demand that their personal information be erased from the register. In addition, they have the right to demand a register record and to request that incorrect information should be corrected (167).

In the qualitative study (Paper III), eligible participants received oral and written information on the aims of study before deciding whether or not to participate. Informed consent was obtained before the interview took place. The participants were also informed that they could withhold their participation at any time without affecting their further treatment. The hidden identity and confidentiality of the participants was assured throughout the research process.

In paper IV, eligible participants received written information on the aims of the study, including assurances that the questionnaire was for research purposes and that participation was voluntarily. They were also assured that their individual integrity would be protected. They were also informed that none of the healthcare providers would have access to their answers to the questionnaire.
RESULTS

PAPER I

Vaginal hysterectomy was performed as the single operation in about 80% of cases and an additional procedure (repair of cystocele or rectocele, anti-incontinence surgery) was performed in 17% of the cases. Complications resulting in reoperation or re-admission were defined as severe complications, and were reported in 3% of cases. The complications consisted mainly of intra-abdominal bleeding and vaginal vault haematomas or infections. We found no statistically significant differences between patients with severe complications and the rest of the study sample concerning medication, preoperative functional state according to the ASA, operative difficulties such as adhesions or presence of endometriosis, or perioperative complications. Subjects with severe complications were younger (p = 0.001), had fewer concurrent diseases (p = 0.007), and had a shorter operative time (p = 0.003) than women with no complications. Furthermore, there were no statistically significant differences in frequency of reported complications between women who had vaginal hysterectomy alone and women who had a concomitant procedure (p = 0.93).

Patient-reported time to return to daily activity showed no differences between age groups and over 50% of the women in each age group had returned to their daily activities within one week of surgery.

Effects of surgery on sexual activity and urinary symptoms were evaluated using identical questions and these were answered by the subjects both preoperatively and six months postoperatively. Patient-reported sexual activity is listed in Table 5. The number of women reporting intercourse had increased by 20% (from 244 to 292 cases; p = 0.006). The number of women who had been sexually inactive prior to surgery and who had resumed sexual activity after surgery was four times higher than women who had been sexually active prior to surgery and who had not resumed sexual activity six months postoperatively. Prior to the surgery, only 3% (n = 31) reported dyspareunia that was estimated to be ≥ 3 according to VAS and the corresponding figure after surgery was 2% (n = 18). The difference was not statistically significant.

Table 5. Sexual activity* reported by patients preoperative and postoperative.

<table>
<thead>
<tr>
<th>6 months postoperative</th>
<th>Yes, n</th>
<th>No, n</th>
<th>Total, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, n</td>
<td>228</td>
<td>16</td>
<td>244</td>
</tr>
<tr>
<td>No, n</td>
<td>64</td>
<td>312</td>
<td>376</td>
</tr>
<tr>
<td>Total, n</td>
<td>292</td>
<td>328</td>
<td>620</td>
</tr>
</tbody>
</table>

*Sexual activity was reported by answering to the question ‘Have you had coitus in the past three months?’

Table 6 lists patient-reported urinary symptoms. A total of 679 subjects answered the questions regarding urinary symptoms in both the preoperative and the postoperative questionnaire. In
the preoperative questionnaire 259 subjects (38%) reported urinary symptoms such as urgency, urge incontinence, and SUI. Six-month postoperatively, this response was reduced to 30% (n = 204) and the differences was statistically significant (p = 0.002). However, among women who had not had urinary symptoms before surgery, 20% reported urinary symptom postoperatively. Approximately 50% of the subjects who had UI preoperatively became continent postoperatively; however, 14% (76/545) developed UI and most of them had de novo stress incontinence (58/545). Urge incontinence was reduced by 60%; however, almost 50% of the subjects with postoperative urge incontinence were continent preoperatively. Symptoms of urinary urgency were reduced in 50% of those reporting it preoperatively, but half of those with postoperative urgency had not reported symptoms of urgency preoperatively. The number of subjects complaining of SUI was doubled (n = 104) compared to preoperatively (n = 50). Postoperatively, new onset of urgency, urge incontinence, and SUI was reported by 6%, 3%, and 11% of patients, respectively.

**Table 6. Urinary symptoms reported by patients, preoperative and six months postoperative.**

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>6 months postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>No reported symptoms</td>
<td>336 (49.5)</td>
<td>420 (61.8)</td>
</tr>
<tr>
<td>Urgency</td>
<td>78 (11.5)</td>
<td>125 (18.4)</td>
</tr>
<tr>
<td>Urge incontinence</td>
<td>40 (5.9)</td>
<td>84 (12.4)</td>
</tr>
<tr>
<td>Stress incontinence</td>
<td>21 (3)</td>
<td>50 (7.4)</td>
</tr>
<tr>
<td>Total</td>
<td>475 (70)</td>
<td>679 (100)</td>
</tr>
</tbody>
</table>

All values are expressed as number (%)

Of the subjects who rated the symptom of vaginal heaviness on the VAS scale as being above 80% of the length of the scale, i.e. VAS 4 and 5 (n = 262) preoperatively, 73% expressed no symptoms of heaviness in the six-month follow-up questionnaire (95% CI: 2.32–2.63; p < 0.001), and 81% had no symptoms irrespective of the previous grade of heaviness.

**PAPER II**

The background characteristics of the subjects who underwent surgery under different forms of anaesthesia showed that the subjects who had been exposed to surgery using general anaesthesia had been younger, healthier, and had smoked more frequently.

We found a wide variation in the prevalence of use of LA in cystocele surgery in relation to the cystocele operation volume per hospital. Length of hospital stay, duration of use of postoperative pain-killing drugs, and time to return to daily activity were shorter in patients who underwent operation under LA compared to one or both of the other two forms of anaesthesia (p < 0.001, p < 0.001, and p = 0.012, respectively). In-dwelling catheter used less frequently in women who underwent surgery with LA compared to women undergoing surgery with the other forms of anaesthesia (p < 0.001). There was no significant difference regarding perioperative complications and patient-reported complications between different forms of anaesthesia (p = 0.4 and p = 0.35 respectively). After conducting a weighted linear regression, we found that an increase in the proportion of use of LA by 1% decreased the proportion of inserted in-dwelling catheters by
0.5% (95% CI: -0.778 to -0.25; p < 0.001). The model explained 38% of the variation in the proportion of inserted in-dwelling catheters. Furthermore, an increase in the proportion of use of LA by 1% reduced the length of hospital stay by 0.007 days (95% CI: -0.013 to 0; p = 0.029). The model explained 17% of the variation in length of hospital stay. By excluding one hospital (an outlier), 27.6% of the variation could be explained (p = 0.005).

In order to evaluate the effect of surgery on symptoms of UI and related to anaesthesia, subjects who reported UI pre- and postoperatively were investigated (n = 978). UI (of any kind) was resolved in 43% of subjects who reported this condition preoperatively (n = 480); however, 11% developed UI postoperatively (Table 7). There was no significant difference in the forms of anaesthesia between the subjects in whom symptoms of UI had developed and those in whom they had disappeared.

### Table 7. Urinary incontinence reported by patients before and after surgery for cystocele.

<table>
<thead>
<tr>
<th>Incontinence preoperative</th>
<th>Incontinence postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, n</td>
<td>No, n</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Incontinence preoperative</td>
<td>Yes, n</td>
</tr>
<tr>
<td>No, n</td>
<td>56</td>
</tr>
</tbody>
</table>

Preoperatively, 1,095 subjects had reported local symptoms including sensation of a vaginal bulge (LA, n = 411; Regional anaesthesia (RA), n = 306; general anaesthesia (GA), n = 378). Of these patients, 63% (n = 688) did not have this symptom one year after surgery (LA, n = 282; RA, n = 201; GA, n = 205; p = 0.11). However, 23% (n = 250) of the subjects with preoperative symptoms of vaginal protrusion had reported a persistent symptom one year after surgery (LA, n = 109; RA, n = 66; GA, n = 75; p = 0.18). There was no significant difference regarding the form of anaesthesia.

We conducted a univariate and multivariate regression analysis to investigate the characteristics that were significantly associated with patient satisfaction. Relevant variables related to patient satisfaction were tested one by one in separate univariate analyses. In the univariate analysis, variables with significant association were age, length of hospital stay, surgery due to relapse, and patient-reported complications. These significant variables were tested in the multivariate logistic regression analysis and entered in a stepwise approach. At this stage of analysis, age (≥ 50 years) and patient-reported complications turned out to be independent variables for patient satisfaction (OR 3.05; 95% CI: 1.36–6.82 and OR 0.21; 95% CI: 0.12–0.36, respectively). There was no association between patient satisfaction and the anaesthesia method. There was a correlation between advanced age and/or few reported complications on the one hand and high patient satisfaction on the other.

### PAPER III

In-depth interviews of subjects with POP who were awaiting surgery revealed the process from recognition of vaginal prolapse to action, which was seeking healthcare. The theme defining this process was labelled ‘process of comprehension and action’. The main findings of this study were identification of two categories and 11 sub-categories acting as promoting or restraining factors to seeking healthcare. Categories were labelled ‘obstacles to seeking healthcare’ and ‘facilitators to
seeking healthcare’. Subcategories connected with a category had their main actions as facilitator or obstacle. However, some of the subcategories also exerted the opposite effects, but to a lesser extent. Factors exerting a negative influence on healthcare seeking were:

- **Absence of information** at the individual level, as well as in a societal arena.
- **Blaming oneself** for having prolapse due to not being active in pelvic floor training and because of all the heavy physical work performed earlier in life.
- **Feeling ignored by the doctor** at previous consultations and their symptoms had not been confirmed, which made the subjects doubt their own perceptions of the condition.
- Prolapse was considered a *covert condition*; subjects were uncertain about what condition they were suffering from until the vaginal mucosa was exposed.
- Informants found different coping mechanisms in order to *adapt to successive impairment*.
- Vaginal prolapse was seen to be a condition of relatively little importance compared to other medical conditions, or other problems they experienced in their social lives. The subjects tended to *trivialise the symptoms and to de-prioritise their own health*.

Factors facilitating healthcare-seeking action were:

- Through supportive communication with partners or others who were more knowledgeable about the condition, the subjects were *confirmed and supported* to seek medical advice.
- Vaginal prolapse was perceived as a sign of ageing by some subjects and they had *difficulty in accepting an ageing body*.
- Some subjects expressed *that they felt sexually unattractive* because of the alterations they experienced in this intimate part of the body.
- Feeling of ‘a lump coming out’ or experience of the functional changes in the bladder and bowel was expressed as *having an unnatural body* by the subjects.
- When the subjects’ social and leisure activities were affected, they *reached the point of action* which was seeking healthcare. Sometimes a triggering event such as post-menopausal bleeding or a triggering person (for example, a midwife) encouraged them to seek healthcare.

**PAPER IV**

Of the 561 participants who answered a web-based questionnaire, duration of symptoms for more than a year was reported by 64% of the women in the prolapse group, 94% in the incontinence group, and 77% in the hysterectomy group. Among the reasons for seeking healthcare, *interference with physical activity* and *increasing symptoms* were the reasons most cited by all three groups of participants (Table 8). Thirty per cent of participants in the prolapse group, 20% in the incontinence group, and 40% in the hysterectomy group reported *interference with sexual activity* as a reason for seeking healthcare. Almost 50% of the women in the prolapse group, 25% of the women in the hysterectomy group, and 30% of the women in the incontinence group had not found that earlier treatments had had any significant effect.
Table 8. Reasons for not seeking health care earlier and reasons for seeking health care currently.

<table>
<thead>
<tr>
<th>Reasons for not seeking health care earlier</th>
<th>Groups of participants</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prolapse (n = 138)</td>
<td>Incontinence (n = 152)</td>
</tr>
<tr>
<td>Condition was not troublesome</td>
<td>53 (38)</td>
<td>49 (32)</td>
</tr>
<tr>
<td>Advised to wait*</td>
<td>34 (25)</td>
<td>27 (18)</td>
</tr>
<tr>
<td>Did not know condition was prolapse†</td>
<td>26 (19)</td>
<td></td>
</tr>
<tr>
<td>Embarrassed to talk about condition</td>
<td>22 (16)</td>
<td>53 (35)</td>
</tr>
<tr>
<td>Did not know condition could be treated</td>
<td>16 (12)</td>
<td>49 (32)</td>
</tr>
<tr>
<td>Family matters</td>
<td>13 (9)</td>
<td>18 (11)</td>
</tr>
<tr>
<td>Unpleasant being gynecologically examined</td>
<td>10 (7)</td>
<td>7 (5)</td>
</tr>
<tr>
<td>Could not take time off from my job</td>
<td>8 (6)</td>
<td>8 (5)</td>
</tr>
<tr>
<td>Future pregnancy was planned</td>
<td>5 (4)</td>
<td>8 (5)</td>
</tr>
<tr>
<td>Financial loss due to sick leave</td>
<td>3 (2)</td>
<td>4 (3)</td>
</tr>
<tr>
<td>Other reasons</td>
<td>5 (4)</td>
<td>12 (7)</td>
</tr>
<tr>
<td><strong>Total number of responses</strong></td>
<td>190</td>
<td>223</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reasons for seeking health care currently</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prolapse (n = 138)</td>
<td>Incontinence (n = 152)</td>
<td>Hysterectomy (n = 143)</td>
</tr>
<tr>
<td>Increasing symptoms</td>
<td>76 (55)</td>
<td>86 (57)</td>
<td>77 (54)</td>
</tr>
<tr>
<td>Interference with physical activity</td>
<td>60 (44)</td>
<td>100 (66)</td>
<td>72 (50)</td>
</tr>
<tr>
<td>Interference with sexual activity</td>
<td>44 (32)</td>
<td>34 (22)</td>
<td>56 (39)</td>
</tr>
<tr>
<td>Earlier treatment was not adequate</td>
<td>34 (25)</td>
<td>43 (28)</td>
<td>64 (45)</td>
</tr>
<tr>
<td>Encouraged by other person†</td>
<td>25 (18)</td>
<td>42 (28)</td>
<td>22 (15)</td>
</tr>
<tr>
<td>Interference with work activity</td>
<td>22 (16)</td>
<td>33 (22)</td>
<td>61 (43)</td>
</tr>
<tr>
<td>Offered surgery earlier but decided to wait</td>
<td>16 (12)</td>
<td>7 (5)</td>
<td>18 (13)</td>
</tr>
<tr>
<td>Other primary reason</td>
<td>10 (7)</td>
<td>6 (4)</td>
<td>5 (4)</td>
</tr>
<tr>
<td>Other reasons</td>
<td>3 (2)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total number of responses</strong></td>
<td>287</td>
<td>351</td>
<td>375</td>
</tr>
</tbody>
</table>

All values are expressed as number of responses and percentage of women responding; n (%). NS = nonsignificant
*By healthcare provider
†Answered only by women undergoing surgery for POP
‡Including healthcare personnel
§Applying Bonferroni, nonsignificant

The single most cited reason for not seeking healthcare earlier in the hysterectomy group and the prolapse group was that the condition had not been troublesome. However, embarrassment in talking about my condition and did not know that my condition could be treated constituted nearly 50% of the responses in the incontinence group compared to the other two groups (p < 0.001). Twenty per cent of the women in the prolapse group did not know that the symptoms were related to
Results

Furthermore, one out of five to one out of four women were recommended to defer surgery by healthcare providers at a previous consultation.

Participants’ responses to the question ‘what is vaginal prolapse?’ were classified into six categories (Table 9). The categories of causes included: vaginal delivery; heavy lifting; weakness in muscle/connective tissue; age; obesity; heredity; menopause; insufficient pelvic floor training; previous gynaecological surgery; delivery of macrosomic infant; and constipation. In all three groups, the majority of responses regarding description of vaginal prolapse were related to vaginal bulging. The most cited causes of vaginal prolapse in all three groups were vaginal delivery, heavy lifting, and weakness in the muscle and connective tissues. The participants in the vaginal prolapse group also reported other causes more frequently, for example menopause and heredity (p = 0.004 and p < 0.001 respectively). Up to 15% of the participants reported that not being active in pelvic floor training was a cause of vaginal prolapse. Women in the reference groups reported “don’t know” more frequently regarding description and causes of prolapse than the prolapse group (p = 0.004 and p < 0.001 respectively).

Table 9. Examples of participants’ descriptions of vaginal prolapse.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| Vaginal bulging                 | When vagina cannot stay inside and is falling out  
Uterus is falling down  
Bowel, urinary bladder or uterus bulge in the vagina |
| Vaginal discomfort              | Something rubs; it feels uncomfortable                                                        |
| Vaginal pressure                | Feeling that something presses on vagina  
Sense of pressure                                                                                     |
| Weakness in muscle/connective tissue | Weakness of vaginal muscle and suspension device  
Weakness of the muscle in the vagina                                                                 |
| Urinary/bowel symptoms          | Having difficulty emptying the bladder and evacuating the bowel  
You have to help yourself manually to empty the bowel content  
When you have an urinary leakage                                                                 |
| Visible                         | Uterus is falling down and it is visible at the entrance to the vagina  
The vaginal wall is falling outside                                                                 |

The sources of information on their own condition differed significantly between the three groups. The prolapse group gained their information from the Internet, healthcare providers, and family/friends to a lower degree than the reference groups (p = 0.008, p < 0.001, and p = 0.007 respectively). However, participants in the incontinence group gained their information from brochures and public media (the daily press, weekly magazine, and TV/radio) to a higher degree than the other two groups. Furthermore, participants in the prolapse group reported significantly fewer sources of information on their own condition than the other two groups (p < 0.001).
Comparison of the responses between the participants who answered our questionnaire on Web (n = 561) and those who responded on paper (n = 79) showed the same pattern regarding healthcare-seeking behaviour, description of POP, causes of POP, and source of information. However, the participants in the prolapse group and the incontinence group who used a paper questionnaire were older and had a lower level of education than the participants in the prolapse and incontinence groups who answered the WBQ. Furthermore, the participants in the prolapse group and the incontinence group who used a paper questionnaire had used the Internet less frequently to obtain information about their own condition than the women in these two groups who had used the WBQ (data not shown).
GENERAL DISCUSSION

The most interesting findings of this thesis were the patient-perceived outcomes after vaginal hysterectomy, showing that the overactive bladder symptoms (e.g. urge incontinence and urgency) were improved; however, a proportion of subjects presented with a new onset of urinary symptoms. Sexual activity increased in 20% of the subjects and symptoms of vaginal heaviness were cured for the majority of patients after vaginal hysterectomy. Severe perioperative and postoperative complications occurred in 3% of cases. Furthermore, comparison of short-term follow-up after cystocele repair surgery in relation to different anaesthesia used did not reveal that there were any disadvantages of using LA. POP surgery can therefore be performed safely with LA. In-depth interviews with subjects with POP explored different factors that might act as facilitators or inhibitors in seeking healthcare. One of the inhibitors to seeking such care was insufficient information about POP in the societal arena. The hypothesis generated was tested in a further study, and we found that women with POP had less access to information in brochures and from the public media regarding vaginal prolapse than women awaiting surgical procedure for incontinence.

EFFECTS OF POP SURGERY ON SYMPTOMS

Few studies have evaluated the effects of vaginal reconstructive surgery on the resolution of overactive bladder symptoms in women with prolapse (79, 171-173). Retrospective review of the medical records of women with grade II or higher prolapse and urge incontinence who have undergone POP surgery has shown that urge incontinence can become resolved after surgery in 63% of subjects (171). Resolution of overactive bladder symptoms has been reported in 50–80% of patients after transvaginal surgery of advanced prolapse and anterior vaginal repair (79, 171-173). Weber et al. showed that anterior colporrhaphy could result in resolution of SUI in 73% of cases (79). New onset of urgency, urge incontinence, and SUI after anterior vaginal repair was reported in 26%, 14%, and 8% respectively in that study (79). Resolution of urgency and urge incontinence symptoms in paper I was found to be comparable to the results of earlier studies (79, 171-173). However, in paper I new onset of urgency, urge incontinence, and SUI was found in 6%, 3%, and 11% of the patients respectively. In paper II, symptoms of UI were resolved in 43% of subjects who reported this symptom preoperatively. New onset of UI (of any kind) after cystocele repair surgery in our study was found in 11% of the patients.

It has been debated that a vaginal hysterectomy possibly contributes to the development of urinary symptoms. In a prospective study, De Tayrac et al. compared vaginal hysterectomy for menorrhagia with endometrial ablation and found no differences in the incontinence rate (174). However, Forsgren et al. showed that the risk of SUI was 6 times higher after vaginal hysterectomy for POP than in women who had not had a hysterectomy (1). The increased risk of SUI was almost three times higher subsequent to a vaginal hysterectomy for a non-prolapse indication than in women who had not had a hysterectomy. The occurrence of de novo stress incontinence after a vaginal hysterectomy for uterine descent has been reported in up to 22% of women (111, 175-176), and the corresponding figure in our study (paper I) was 11%.
Urodynamic investigation in patients undergoing prolapse surgery may be valuable in order to diagnose SUI or occult SUI, resulting in selection of the optimal treatment strategy (76). This treatment strategy includes either a combination of prolapse and stress incontinence surgery or prolapse surgery initially and re-evaluation of possible stress incontinence afterwards. In patients with vaginal prolapse and occult SUI, there are conflicting data about the reduction of SUI symptoms if prolapse surgery is combined with anti-incontinence surgery (177-178). Liang et al. showed a reduction of 56% in the symptoms of SUI, while Tayrac et al. showed a reduction of only 12% if prolapse surgery was combined with stress incontinence surgery. Both studies showed an increased risk on overactive bladder symptoms after the combination surgery (177-178). Against this background, gynaecologists should discuss both treatment options with their patients, and their advantages and disadvantages.

In paper II, cystocele repair surgery provided relief of symptoms related to vaginal protrusion in 63% of the subjects. However, 23% reported subjective symptoms of persistence of a vaginal bulge one year after surgery. Repair of cystocele is one of the most challenging aspects of pelvic reconstructive surgery, due to high recurrence rates related to the surgery (79). There have been few studies on subjective outcome after cystocele surgery. Anterior colporrhaphy for repair of cystocele has shown a variety of objective success rates (41–96%) (179).

There are conflicting data concerning the effects of pelvic floor surgery on sexual function. Studies have demonstrated that sexual life can be improved (95, 180), remain unaltered, or become worse (181-182). In our study (paper I), vaginal hysterectomy for prolapse had a positive effect on sexual activity, and dyspareunia was not common in the study sample. In an earlier study, mild to severe dyspareunia was reported in up to 20% of women after a vaginal hysterectomy for uterovaginal prolapse (112). However, in that study 90% of the subjects were subject to posterior colporrhaphy and perineorrhaphy, which might explain the higher rate of dyspareunia. Other studies have shown that sexual function is improved after vaginal hysterectomy for uterine prolapse, due to resolution of the prolapse symptoms (180, 183).

In a randomised trial, improvement in all urogenital domain scores (UI, overactive bladder, prolapse) and quality of life (mobility, physical function, social functioning, emotional functioning, and embarrassment) was found one year after a vaginal hysterectomy because of vaginal prolapse (184).

**COMPLICATIONS AFTER VAGINAL HYSTERECTOMY**

Severe complications that resulted in re-admission or reoperation were reported in 3% of the case (paper I). Vault haematoma/abscess constituted 1% (9/941) of all complications. This is in accordance with results from recently published studies (185-186). In paper I, the majority of severe complications were attributed to infections. Younger women presented more severe complications such as vaginal vault abscess, probably due to the fact that bacterial vaginosis was more common in this group of women, making them more susceptible to postoperative infections (187). The overall complication rate reported by patients was 30%; however, surgeons assessed the patient-reported complications to be a medical complication in only 14% of cases. This reflects the fact that patients and professionals have different frames of reference in their assessment of complications. Some complications reported by patients were ‘normal’ and expected conditions after surgery.
VAGINAL HYSTERECTOMY FOR TREATMENT OF UTERINE DESCENT

Vaginal hysterectomy combined with apical suspension is usually considered to be the first choice for treatment of uterine descent (109). In a review article comparing complications and anatomical outcomes after vaginal hysterectomy with those after other transvaginal uterus-preserving methods (the Manchester procedure or sacrospinous hysteropexy), vaginal hysterectomy was found to have higher morbidity (blood loss, infection) than the Manchester procedure (186, 188-189). When comparing vaginal hysterectomy with sacrospinous hysteropexy, the morbidity associated with vaginal hysterectomy is longer operating time, longer recovery time, and more blood loss (190-192). After adjusting for age and BMI, there was a threefold higher risk of urge incontinence and overactive bladder symptoms after vaginal hysterectomy than after sacrospinous hysteropexy (191). Uterus-preserving procedures are equally effective with regard to anatomical apical cure and recurrent prolapse surgery (including apical or any prolapse) compared to vaginal hysterectomy (186).

However, a retrospective study has shown that vaginal hysterectomy and uterus-preserving abdominal sacrocolpopexy have similar results with respect to morbidity of the surgical procedure and risk of recurrence of vaginal prolapse (193). A randomised, controlled trial has shown that vaginal hysterectomy is superior to uterus-preserving abdominal sacrocolpopexy with respect to postoperative urogenital function and reoperation rate (184). The same author reported in an RCT study that vaginal hysterectomy is associated with less pain, better mobility, and better quality of life during the first 6 weeks of recovery compared to the uterus-preserving abdominal approach (194).

A large Swedish cohort study revealed that vaginal hysterectomy in women with POP may be associated with a 5 times higher risk of subsequent POP surgery than in women who do not have a hysterectomy (1). Paper I presented some short-term results from the patient’s point of view. The anatomical cure rate was not presented.

There is no definitive golden standard procedure for treatment of uterovaginal prolapse. Thus, the surgeon’s skill in different surgical techniques, patient’s preference, age, and comorbidity all play an important roll in the choice of operation for uterine prolapse.

IMPACT OF ANAESTHESIA ON PROLAPSE SURGERY

In choosing an anaesthetic technique, issues related to safety and efficiency must be considered (124). In paper II, short-term outcomes after cystocele surgery in relation to different anaesthetic methods did not reveal any disadvantage of surgery using LA. Advantages of LA (Paper II) were a short hospital stay and fast recovery time. However, length of hospital stay and the speed of the recovery period are related to many factors, e.g. age, preoperative morbidity, distance to the hospital, and the doctor’s opinion and attitude regarding the convalescence period (195-196). Fast-track surgery using a multi-modal rehabilitation care program with a well-defined scheme for the convalescence period has been shown to hasten postoperative recovery, reducing the hospital stay period and morbidity (197-200). Fast-track surgery has been used for colon surgery, laparoscopic surgery, and vaginal prolapse surgery (199, 201).

The choice of anaesthesia at surgery appears to be related to the individual patient and surgeon’s preference/experience and also to the prevailing tradition at hospitals. Earlier studies have investigated the feasibility of using LA in prolapse surgery and showed a high degree of patient satisfaction (2, 120). However, the results from these studies were based on surgeons with a great
deal of experience of POP under LA. The results of paper II show that cystocele repair surgery can be performed safely with LA and that patient satisfaction is not related to anaesthetic method. Long-term follow-up in terms of recurrence rate is of interest concerning the use of LA in POP surgery. However, most studies investigating LA in prolapse surgery have not had a long follow-up period (2-3, 120, 122-123).

QUALITATIVE RESEARCH AS A COMPLEMENTARY TOOL

While qualitative and quantitative research may investigate similar topics, each will address different kinds of questions (156). Qualitative research is suitable for gaining an in-depth understanding of a phenomenon. Qualitative research may explain why the result of quantitative research based on a large group of women may be irrelevant to subgroups (152).

Qualitative research complements quantitative research in urogynaecology (155). For example, a vital stage in questionnaire research is validation of individual questions by performing interviews to check the meaning of words to be used.

Srikrishna et al. emphasise the importance of qualitative research when exploring experiences and expectations of women with POP (202). While a disease-specific QOL questionnaire allows us to assess patients' inconvenience, these questionnaires may lack the sensitivity to explore individual experiences. In paper III, women tended to minimise the importance of symptoms and this is consistent with findings in earlier studies (134, 203). In addition, in our study (paper III) women's self-image was affected, their social activities were negatively influenced, and insufficient knowledge about vaginal prolapse was expressed. The results were consistent with those of another qualitative study (204).

Most previous research regarding sexuality in women with POP has focused on sexual function, including frequency and pain during intercourse. Qualitative studies can address another aspect of sexuality in women suffering from POP and how they experience their body and how this condition may influence their sexual life. In paper III, some informants expressed that they did not feel sexually attractive to their partners. This observation is consistent with findings in another qualitative study of women with POP of stage II or more (205). However, in contrast to our study, participants who were single in that study was not interested in dating/finding a sexual partner; a group of women who were particularly affected by POP in our study.

The findings in the qualitative study (paper III) generated a hypotheses consisted of insufficient level of knowledge about POP at an individual level, as well as insufficient information on POP in the public arena. Thus, the findings from paper III were tested further in a quantitative study (paper IV) to estimate the extent of the problem among women undergoing surgery for POP.

HEALTHCARE-SEEKING BEHAVIOUR

Many factors, e.g. age or effect on QOL, are known to affect care seeking for UI (206-208) but little is known about POP healthcare-seeking. Some studies have suggested that only 10–20% of women with POP seek healthcare for their problems (209). Burigo et al. showed that older adults with UI did not report the condition to their doctor due to being ashamed, but the severity of incontinence and physical disability were the strongest predictors of healthcare-seeking behaviour (207). Marital status, gender, income, employment status, and educational level were not associated with seeking treatment for UI in that study.
In our study (paper IV), 25% of women with POP initially had tried conservative treatment but gradually realised that this treatment was not sufficient. In accordance with the previously performed study in paper III and studies investigating healthcare-seeking behaviour in incontinent women (135, 207-208), it was increasing symptoms and interference with physical and sexual activity that made women seek healthcare. Furthermore, in line with other studies (134, 207, 210-211), one third of the subjects in the incontinence group in paper IV reported they were embarrassed to talk about their condition, and the same proportion of subjects were unaware of the fact that the condition could be treated.

Sexual life was affected in one out of three women with POP who sought healthcare in our study (paper IV). This observation is in line with earlier results (72, 84). It is notable that personal economic loss and employment-related issues were not common reasons for not seeking healthcare in our study.

**DESCRIPTION AND CAUSES OF POP REPORTED BY SUBJECTS**

In paper IV, POP was described by subjects with and without symptoms of vaginal prolapse. The most prevalent description of POP among the participants was ‘vaginal bulging’. The most common reported causes of POP were ‘vaginal delivery’, ‘heavy lifting’, and ‘weakness in muscle/connective tissue’. Participants’ descriptions of POP in paper IV were almost in accordance with the existing descriptions in the scientific literature (9, 62, 64, 75, 212). Previous studies have demonstrated that the presence of a vaginal bulge is the symptom most strongly correlated with the presence of advanced POP (35, 67). On average, participants in the prolapse group reported a higher number of causes related to vaginal prolapse, and they also reported other causes of prolapse, e.g. menopause and heredity, more frequently; thus, they seemed to be more oriented to this condition.

‘Not being active in pelvic floor exercise’ was reported by the participants as cause of prolapse. Avulsion of the levator ani muscle during vaginal childbirth is associated with development of POP (27), and furthermore, neuromuscular injury that occurs during vaginal birth can contribute to UI and POP (28-29). Pelvic floor training is commonly used as the first step in the treatment of urinary and fecal incontinence (96-97). However, the effects of pelvic floor training in the prevention of POP are uncertain (98).

**SOURCES OF INFORMATION ON SPECIFIC CONDITIONS**

Sources of information on the subjects’ own condition differed significantly between the participants in paper IV. Besides the information that participants received from the healthcare providers, they also consulted family and friends and searched actively on the Internet for information. Subjects with vaginal prolapse had less access to information through brochures and public media than women in the incontinence group. When comparing the prolapse group with the reference groups, we found that they received information from healthcare providers less frequently. In addition, subjects in the prolapse group reported significantly fewer sources of information than the reference groups. We can conclude that there appeared to be a lack of information on prolapse in the public arena. This is in line with the findings in our previous study in paper III.

The participants in the incontinence group and the prolapse group, who answered our questionnaire on paper, used the Internet less frequently to obtain information. This might correspond
to the fact that they were older and had a lower level of education. Interestingly, subjects in the incontinence group had more access to information brochures and public media than the subjects in the other two groups. In general, the mass media have helped to publicise UI, particularly by advertising anti-cholinergic medication and sanitary pads. Similar publicity does not exist for POP. In Sweden, subjects suffering from incontinence have access to the incontinence association through a webpage (213), where they can gain information. This channel of information is lacking for subjects with POP. This observation is in accordance with the findings in paper III.

METHODOLOGICAL CONSIDERATIONS
In this section, some methodological considerations are discussed, firstly regarding the use of secondary data (as in the case of the Gynop-register). Thereafter, each paper is discussed in terms of the strengths and limitations of both primary and secondary data. Factors that affect the value of research on secondary data such as healthcare register data are: the accuracy and degree of completeness of the data registered, completeness of registration of the individuals, the size of the data source, and the possibility of linkage to other data sources (214).

The accuracy and degree of completeness of the data registered
The accuracy of the data registered refers to the idea that a questionnaire measures what it is meant to measure and to do it in a reliable way, i.e. validity and precision (214). The questionnaires used for data collection in the Gynop-register were validated previously and a number of studies from the register have been published in peer-reviewed journals (200, 215-217). Generally, a low response rate poses a threat to the validity of quantitative research (218). The strengths of papers I–II and IV were the high response rate (more than 90%) and the high completeness of the data in the register.

Completeness of registration of the individuals
As previously mentioned, the mean proportion of patients undergoing gynaecological surgery and included in the register was 96% of eligible patients, in accordance with an inspection visit in 15 clinics. Furthermore, we made a comparison of different clinical variables and characteristics of subjects undergoing POP surgery in these 15 clinics, and the remaining 28 clinics that were not inspected regarding inclusion of the patients in the register. All subjects undergoing POP surgery from 2009 to 2010 were included in the comparison (Table 10). No statistically significant differences were found. We can therefore conclude that our selected group of patients in the studies included in this thesis did not diverge from those in the clinics that had been inspected by the Board of the Gynop-register.

One way of estimating the degree of completeness of records in the Gynop-register is to compare the data source with other independent reference sources where the whole of the target group is registered (214). We compared the number of patients admitted in hospitals for POP surgery and registered in the Gynop-register during 2009 with the number of patients undergoing POP in the inpatient care, based on the Swedish Inpatient Register. We found that the overall number of patients registered in the Gynop-register was in line with the number of patients in the Swedish Inpatient Register.
**Table 10.** Characteristics of women who underwent prolapse surgery during 2009, at clinics being inspected versus not being inspected by the Board of the Gynop-register.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A (n = 1609)</th>
<th>Group B (n = 2057)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>63.8 ± 11.1</td>
<td>63.6 ± 11.2</td>
<td>NS</td>
</tr>
<tr>
<td>BMI</td>
<td>26.3 ± 3.86</td>
<td>26.2 ± 3.79</td>
<td>NS</td>
</tr>
<tr>
<td>Parity</td>
<td>2.56 ± 1.1</td>
<td>2.58 ± 1.1</td>
<td>NS</td>
</tr>
<tr>
<td>Number of pregnancy</td>
<td>3.05 ± 1.51</td>
<td>3.07 ± 1.5</td>
<td>NS</td>
</tr>
<tr>
<td>Employed</td>
<td>630 (39)</td>
<td>750 (36)</td>
<td>NS</td>
</tr>
<tr>
<td>Smoker</td>
<td>156 (10)</td>
<td>203 (10)</td>
<td>NS</td>
</tr>
<tr>
<td>Co-morbidity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>80 (5)</td>
<td>123 (6)</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension</td>
<td>621 (39)</td>
<td>673 (33)</td>
<td>0.01*</td>
</tr>
<tr>
<td>Cardio-vascular disease</td>
<td>176 (11)</td>
<td>197 (10)</td>
<td>NS</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>279 (17)</td>
<td>350 (17)</td>
<td>NS</td>
</tr>
</tbody>
</table>

All values are expressed as mean ± standard deviation or number and (%).

Group A; women who underwent surgery in 15 clinics which has been inspected regarding inclusion of patients. Group B; women who underwent surgery in 28 clinics which has not been inspected.

*Applying Bonferroni, nonsignificant

**The size of the data source**

The size of the data source, i.e. the number of people and the number of variables registered, may have an impact in the results (214). In a large data source, even small associations will give statistically significant results (214). Relating the size of the data source to the clinical relevance of any differences is therefore more important in such cases than simply looking at the p-values (214). In statistics, a method used to address the problem with multiple comparisons is the Bonferroni correction, which was used in the quantitative studies included in the thesis.

**Possibility of linkage to other data sources**

In Scandinavia, each person is assigned a unique personal registration number at birth, allowing linkage between several data systems. The Gynop-register is cross-linked to the Cause of Death Register, the register of the total population, and the Inpatient register.

**Strengths and limitations**

The study samples in papers I–II and IV consisted of subjects who underwent surgery for POP and who were registered in the Gynop-register. Referring to Table 4, the Gynop-register has good coverage of clinics performing POP surgery in Sweden, and the register covers 51% of the patients undergoing POP surgery in the inpatient care. We have no reason to question the idea that women undergoing surgery for POP and who are registered in the Gynop-register would differ from women undergoing surgery for POP and who are not registered in the Gynop-register. Inclusion of the subjects in the register was done by a secretary or an operations planner who did not make any medical judgement of the patients. With this strategy, every eligible patient had the same opportunity to be included in the register and in the studies, and thus we consider that there was probably no selection bias regarding inclusion of patients in the register.
Papers I and II

In paper I, we used data from the hysterectomy section of the Gynop-register on subjects who underwent vaginal hysterectomy for the indication POP. This section of the register has the most extended coverage concerning gynaecological surgery. The limitation of paper I was that there was no information included in this section of the register on the stage of the prolapse or on the type of vaginal apical suspension performed during surgery. The decision to perform vaginal hysterectomy (with the indication prolapse) was made by individual gynaecologists. There is evidence that vaginal apical correction using mesh has a higher rate of complications requiring reoperation than the traditional vaginal surgeries and sacrocolpopexy (219). Thus, we could not discriminate whether some of the complications were related to the mode of the apical suspension procedure.

In paper II, there were missing data on registration of current use of the anaesthesia method. In order to avoid selection bias for registration of the anaesthesia method in paper II, we chose a cut-off limit of 60% for registration of anaesthesia for including clinics in the study. All the clinics (n = 4) that had more than 40% missing data concerning registration of anaesthetic method used for surgery were excluded. With this approach, we excluded 175 operations in which the anaesthesia method was registered in only 55 subjects. The cut-off point of 40% for excluding clinics was chosen because it was the largest gap seen between clinics regarding missing information for registration of anaesthetic method. Among eligible women in the study, the information about the type of anaesthesia method used at surgery was not registered for 200 subjects. We therefore analysed the characteristics of the subjects included in the study (n = 1,364) and the subjects who were excluded because of missing information on use of anaesthesia (n = 200), and we found no statistically significant differences. Thus, we might be able to conclude that the anaesthetic method was not registered by chance.

In paper I, the non-response analyses were performed by manually retrieving data from the medical records of those who had not responded to the follow-up questionnaire (n = 36). No severe complications could be identified among the non-respondents. Because of the high response rate, the issue of ‘non-response’ bias was not of importance in paper II.

An advantage of a retrospective study design is that all the events under the study period have already occurred. The conclusions can therefore be drawn more rapidly and they can scarcely be influenced by the hypothesis (151). The other strength of these studies was that they reflected the ‘routine’ healthcare setting and were focused on patient-perceived results postoperatively. Despite the involvement of different surgeons with different surgical techniques and surgical skills, the complication rate was low.

Paper III

In this paper, we restricted our study to subjects who did not have a history of recurrence of vaginal prolapse because we postulated that recall of earlier symptoms might affect their narratives in the current interview. We used qualitative content analysis because it offers a straightforward method of analysing textual data and provides some specific norms and guidelines for data analysis (161).

The aim in a qualitative research interview is to explore the interviewee’s own framework of meanings and to avoid predetermined structures as far as possible (220). In qualitative research, there is a possibility that the concepts that emerge during the study may be very different from those that have been assumed at the beginning of the research, and the researcher should remain
open to this possibility (220). The strength of our study design was purposive sampling of the informants and the emergent design of the study, which enhanced the quality of the data collected.

In qualitative research, interview data are constructed jointly by the interviewer (investigator) and the interviewee. There is therefore a risk that the pre-understanding of the researcher will influence the analysis and the interpretation of the findings. In order to reduce the risk of bias and challenge the author’s own pre-understanding, the findings were discussed within the research group, who had heterogeneous experiences. The findings were also presented at seminars, leading to new input from those outside the research group. The research group consisted of one urogynaecologist, one gynaecologist, a midwife, and an obstetrician. The last two researchers had substantial experience of qualitative and quantitative research.

An important aspect of credibility in this paper was to present the data and the process of analysis (161). Trustworthiness was further enhanced in this study by independent categorisation during the process of analysis, as proposed by Burnard (221). Another aspect of the credibility of research findings in qualitative research is seeking agreement between co-researchers and informants (161). However, no respondent confirmation (member checks) was conducted in paper III, since the findings were synthesised, decontextualised, and abstracted from individual characteristics. Hence, the informants might not recognise their own contributions to the study. To establish dependability, an open dialogue between researchers was created and interpretation of the data was discussed. The researchers’ judgments about the new data obtained during the study period and similarities and differences of content were consistent over time. Confirmability of this paper was established by leaving a decision trail, i.e. discussing theoretical, methodological, and analytical processes (222). To further visualise the interpretation of the findings, quotations from the text were used to illustrate the experiences of the subjects. Regarding the issue of transferability, the experiences described by the subjects in paper III may be transferred to other women in similar settings.

One limitation of this paper was one interview conducted by the first author who had an ongoing patient-doctor relationship with the informant, who was the youngest of the subjects. There is an assumption that an interviewee who is already a patient may wish to please the doctor by giving the responses she thinks the doctor wants. However, the informant gave one of the most comprehensive narratives in the study material.

**Paper IV**

The strength of this study was that the questionnaire used was developed exclusively for this study, based on the findings from paper III.

The overall response rate was 95% and the response rate in different questions was high (84–99%). The response options in the questionnaire were based on the interview study in paper III and the pre-existing options covered 91–99% of the answers produced. **Belief in getting better with time**, **having other medical conditions that needed treatment first**, **being afraid of surgery**, and **adapting/accepting the condition** were cited by 8% as reasons for not seeking healthcare earlier and they were not captured in the available options.

Subjects who answered a web-based questionnaire were included in the study. This study design might raise concern related to the representativeness of the study sample in relation to the source population. However, we compared participants’ responses gained from the web-based
questionnaire to responses from a small group of participants who answered our questionnaire on paper (n = 79). The same pattern in the responses concerning healthcare-seeking behaviour, and description and causes of POP was found. However, the number of participants who answered the questionnaire on paper was relatively low, which affected the statistical power, so we chose not to present these results in paper IV. In addition, we compared the characteristics of the participants with two groups of non-participants answering a preoperative questionnaire on paper to determine whether the study sample was representative. The first reference group of non-participants were subjects whose e-mail addresses were unknown (n = 426). The second reference group of non-participants were subjects who did not have an e-mail address (n = 997). All non-participants were planned for POP surgery, hysterectomy, or anti-incontinence surgery during the same period as the study period. Significant differences were only found between participants included in study IV and non-participants who did not have an e-mail address, concerning characteristics such as age, hypertension, diabetes, current use of HRT, and menopause (Table 11). However, after performing a multiple logistic regression analysis for each of the dependent variables (mentioned above), we found that age was the only significant variable explaining the differences in the prevalence of hypertension, diabetes, menopause, and current use of HRT between the participants in study IV and non-participants not having e-mail address. Thus, we may conclude that our results are most probably representative of the population of subjects planned for gynaecological surgery because of POP, bleeding disorder, or incontinence.

Table 11. Characteristics of the participants responding a Web questionnaire compared with two reference groups of non-participants responding a paper questionnaire.

<table>
<thead>
<tr>
<th>Variable</th>
<th>A (n = 561)</th>
<th>B (n = 426)</th>
<th>C (n = 997)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>52 ± 10.7</td>
<td>51.5 ± 10.5</td>
<td>62.2 ± 13</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>BMI</td>
<td>27 ± 11.2</td>
<td>26.4 ± 4.7</td>
<td>27.2 ± 4.8</td>
<td>NS</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>3 ± 1.5</td>
<td>3.1 ± 1.7</td>
<td>3 ± 1.8</td>
<td>NS</td>
</tr>
<tr>
<td>Parity</td>
<td>2.5 ± 2.4</td>
<td>2.4 ± 1.08</td>
<td>2.5 ± 1.29</td>
<td>NS</td>
</tr>
<tr>
<td>Previous caesarean section</td>
<td>63 (11)</td>
<td>66 (15)</td>
<td>93 (9)</td>
<td>0.01*</td>
</tr>
<tr>
<td>Smoker</td>
<td>66 (12)</td>
<td>67 (16)</td>
<td>123 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension</td>
<td>123 (22)</td>
<td>88 (21)</td>
<td>343 (34)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>18 (3)</td>
<td>15 (3.5)</td>
<td>79 (8)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Current HRT</td>
<td>124 (22)</td>
<td>101 (24)</td>
<td>298 (30)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Menopause</td>
<td>234 (42)</td>
<td>160 (38)</td>
<td>592 (59)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

All values are expressed as mean ± standard deviation or number and (%)
Note: A = Participants responding a web questionnaire; B = non-participants with unknown e-mail address, responded paper questionnaire; C = non-participants who did not have an e-mail address, responded paper questionnaire; HRT, hormone replacement therapy
Group A was compared with group B and C.
*Applying Bonferroni, nonsignificant
There is an assumption that patients are prone to give what they consider 'the correct answer' to a researcher. We cannot therefore be sure whether participants' description of vaginal prolapse is based on their own understanding or whether it is based on the information they have gained by consulting others or by searching for information on the Internet. This is of particular concern regarding the participants in the reference groups. Participants in the prolapse group were requested to report their sources of information on their condition; however, the source of information regarding description of prolapse among the reference groups was not highlighted. It is possible that we might have captured other aspects of the subjects' perception of vaginal prolapse by expanding the questionnaire to include more questions and/or other question formats, e.g. multiple-choice questions.

In general, when performing prospective studies, following subjects over a long period of time can be problematic due to loss to follow-up (150). Eligible participants in this study were included prior to the surgery and the likelihood of discontinuing the participation was not an issue.
Papers I and II provided results of POP surgery. With patients in focus, we also explored their experiences of vaginal prolapse and its effect on their daily lives in a qualitative study (paper III) in order to search for new, unexplored information. In that study, patients expressed that they had to search actively to find information on vaginal prolapse, and they experienced insufficient information on vaginal prolapse in the public domain. Some women could not relate their symptoms of prolapse. Based on the results from study III, we developed a questionnaire in which perception of vaginal prolapse, source of information on their own condition, and the causes for seeking healthcare, were requested (paper IV). Patients with a planned surgery for POP, UI, or bleeding disorder (resulting in hysterectomy) were included in the study. The latter two groups were used as reference groups in the study.

In paper I, the results of vaginal hysterectomy for the indication prolapse in a ‘routine’ healthcare setting showed few complications. Subjective outcomes concerning symptoms of urgency and urge incontinence were resolved in over 50% of the subjects, and local symptoms of vaginal heaviness and pressure were cured in over 80%. However, the number of subjects who complained of SUI was doubled and the prevalence of new onset of SUI was 11%. Surgery had a positive effect on sexual activity.

In paper II, we found that cystocele surgery using local anaesthesia was comparable to surgery with other anaesthetic methods. Surgery can be performed safely under LA if there are no contraindications or specific patient preferences.

In paper III, one of the obstacles in seeking healthcare was lack of information about POP and lack of confirmation by the physician at a previous consultation. The main facilitators related to seeking healthcare were the feeling of being sexually unattractive and impaired physical ability due to vaginal prolapse. By providing easily accessible information on POP, the possibility of subjects gaining knowledge about their condition can be improved and they may then overcome obstacles to seeking healthcare. Healthcare professionals have a significant role to play in facilitating the process by confirming and informing women about the condition, and counselling them on available treatment options.

In paper IV, we found that women with a planned surgery for prolapse, urinary incontinence, or bleeding disorder (resulting in hysterectomy) generally appeared to have relevant information on POP. However, one out of five women in the prolapse group did not know that her symptoms were related to vaginal prolapse and it was found that they had less access to information brochures than subjects in the incontinence group. We can therefore conclude that the general population might benefit from information about POP and awareness of related symptoms to improve healthcare-seeking behaviour in patients with the condition.
CLINICAL IMPLICATIONS

POP is a common condition in elderly women who might have poor health, and use of invasive anaesthetic methods might therefore be dangerous (223-224). Since repair of cystocele under local anaesthetic is comparable to surgery using other forms of anaesthesia, it is of benefit to patients to perform surgery in LA if there is no contraindication or no specific patient preference. However, local anaesthesia might even be considered in POP surgery of younger women because it allows quicker return to daily activities.

POP has a negative effect on women’s quality of life. Women participating in our study revealed that there is a lack of information on POP in the social arena, and some women could not consider their symptoms as being associated with vaginal prolapse. Healthcare providers have a significant roll in providing patients with adequate information on their condition and on the available treatment options. Furthermore, due to the complex relationship between POP and the existing symptoms, it is important to discuss the effect of surgery on symptoms, and the possibility of occurrence of new symptoms, so that patients are provided with sufficient information preoperatively.
FUTURE RESEARCH

Suggestions for future research in this field:

- Randomised controlled trials comparing long-term outcomes after POP surgery related to different anaesthetic methods.
- Postoperative in-depth interviews with women for whom sexuality has been affected by vaginal prolapse, in order to explore the effect of surgery on sexual life.
- Investigation of the most common surgical method for treatment of uterovaginal prolapse in Sweden.
- Multi-centre studies investigating women's knowledge about prolapse.
- Investigation of patient involvement in decision making before POP surgery, and also the quality of the information that patients receive prior to surgical treatment.
- Studies investigating the influence of different changes of lifestyle on prevention of POP.
- Investigation of the role of improvement of pelvic-floor muscle strength in prevention of POP.
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1: Markera de utbildningar som du har avslutat.

☐ Grundskola (eller folkskola, realskola)
☐ Folkhögskoleutbildning
☐ Gymnasieutbildning
☐ Högskole- eller universitetsutbildning

2: Har du haft symtomen du sökt för i mer än ett år?  ☐ Ja ☐ Nej
Om nej gå till nästa sida, fråga 3.

2a: Antal år ……

2b: Varför sökte du inte tidigare? *Markera ett eller flera svarsalternativ*

☐ Mina besvär har fått stå tillbaka pga andra familjemedlemmars behov.
☐ Ansåg att den ekonomiska förlusten vid sjukkrivning var för stor.
☐ Har sökt tidigare men behandlingen som gavs är otillräcklig.
☐ Bedömde själv att besvären inte var så allvarliga.
☐ Har inte ansett mig kunna ta ledigt från arbetet.
☐ Har sökt tidigare men fått rådet att avvakta.
☐ Obehagligt att bli gynekologiskt undersökt.
☐ Visste inte att besvären kunde behandlas.
☐ Visste inte att besvären var framfall. (besvarades enbart av prolapspatienter)
☐ Känns genant att prata om problemet.
☐ Hade planerat att föda fler barn.
☐ Annat: ……………………………………………………………

2c: Vad är anledningen till att du söker nu? *Markera ett eller flera svarsalternativ*

☐ Provat annan behandling men den ger inte tillräcklig effekt.
☐ Blivit erbjuden operation tidigare men valde att avvakta.
☐ Ökad påverkan på mitt sociala liv (umgång, fritid, sport etc).
☐ Ökad påverkan på mitt arbetsliv (förmågan att sköta arbetet).
☐ Blev uppmanad av annan person att söka.
☐ Ökad påverkan på mitt sex- och samliv.
☐ Sökte egentligen av annan orsak.
☐ Tilltagande symtom
☐ Annat: ……………………………………………………………
3: Misstänkte du att dina symtom och besvär berodde på framfall innan läkare konstaterade att du hade framfall?  
☐ Ja  ☐ Nej (besvarades endast av prolapspatienter)

Om nej, vad trodde du att dina besvär berodde på? Markera ett eller flera svarsalternativ

☐ Urinvägsinfektion/ urinvägsbesvär  
☐ Effekt av tunga lyft eller tungt arbete  
☐ Tidigare graviditeter  
☐ Åldersförändringar  
☐ Förstoppning  
☐ Tumör  
☐ Annat ………………………

4: Är det bestämt att du skall opereras?  
☐ Ja  ☐ Nej  
Om nej, hoppa till nästa sida, fråga 5.

4a: Upplever du att du var delaktig i operationsbeslutet?  
☐ Ja  ☐ Nej  
Om nej, hade du önskat delaktighet i beslutet?  
☐ Ja  ☐ Nej

4b: Har du och din läkare diskuterat operationens effekter på dina symtom?  
☐ Ja  ☐ Nej  
Om nej, hade du önskat sådan diskussion?  
☐ Ja  ☐ Nej

4c: Har läkare informerat dig om operationens eventuella effekt på;
Att tömma tarmen?  
☐ Ja  ☐ Nej  
Om nej, hade du önskat sådan information?  
☐ Ja  ☐ Nej

Att hålla urinen?  
☐ Ja  ☐ Nej  
Om nej, hade du önskat sådan information?  
☐ Ja  ☐ Nej

Att tömma urinblåsan?  
☐ Ja  ☐ Nej  
Om nej, hade du önskat sådan information?  
☐ Ja  ☐ Nej

Att ha samlag?  
☐ Ja  ☐ Nej  
Om nej, hade du önskat sådan information?  
☐ Ja  ☐ Nej

5: Fick du under läkarbesöket möjlighet att ställa de frågor du önskade?  
☐ Ja  ☐ Nej
6: Har du under det senaste året tagit del av någon information om framfall / urininkontinens / menstruations-/blödningsrubbning via:

<table>
<thead>
<tr>
<th>Information Source</th>
<th>Ja</th>
<th>Nej</th>
</tr>
</thead>
<tbody>
<tr>
<td>Släkt, vänner eller bekanta</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Besök inom sjukvården</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informationsbroschyrer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dags-/ kvällspress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veckopress / månadsmagasin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Böcker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radio / TV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annan informationskälla,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Om ja vilken?: ...........................................

7: Framfall är något som många kvinnor får, men det är inte alltid lätt för kvinnan att själv veta att det rör sig om ett framfall.

7a: Beskriv vad du tror att framfall är?: ..........................................................

7b: Vad tror du orsakar framfall?: ..........................................................

Datum för enkätens besvarande...............................