

Summary

Anal incontinence (AI) is a symptom-based diagnosis and involves involuntary loss of solid or loose stool, flatus or faecal urgency defined as the inability to defer defecation. The main aetiology is considered to be related to pregnancy and childbirth. AI is often viewed as a woman's problem, with as many as one in five Norwegian women over the age of 30 experiencing symptoms of AI. Due to the socially debilitating consequences of AI, and that few health professionals routinely ask questions related to patients' continence status, symptoms may be under-reported. Patients with symptomatic AI are reluctant to seek medical advice, and it is estimated that only one in five patients with AI seek medical help. The prevalence of AI increases with age and particularly after menopause. However, findings from other countries suggest that the onset of AI symptoms is often reported in relation to a woman's first pregnancy or delivery. The prevalence of AI in pregnancy and postpartum in Norway was scarcely documented at the start of the project.

The present study is a prospective cohort study conducted in the period May 2009-April 2011. A total of 1571 primiparae were included from the maternity wards at Ostfold Hospital Trust Fredrikstad and St. Olavs Hospital Trondheim. The participants answered questions on standardised questionnaires regarding the prevalence and frequency of AI and how symptoms of AI affected their health-related Quality of Life in late pregnancy and one year after delivery. Sociodemographic and delivery-related data were collected from the participants' hospital records.

The main aim of this study was to estimate the prevalence of AI among primiparous women, and to evaluate the impact of AI on health-related quality of life in late pregnancy and the first year after delivery. More specifically, the aims of the three separate papers were:

Paper I: To evaluate the prevalence and predictors of specific AI symptoms, including urgency, in late pregnancy and one year after delivery.

Paper II: To explore how experiencing different types of AI in late pregnancy affects health-related quality of life among primiparous women.

Paper III: To explore the changes in continence status from late pregnancy and throughout the first year postpartum among healthy primiparae and investigate factors associated with persistent and new onset AI symptoms twelve months postpartum

The results from the three papers were:

Paper I: AI was reported by 37% in late pregnancy, compared to 25% one year after delivery. Urgency was the most frequently reported symptom at both time points. Being unemployed and younger than 22 years at first delivery increased the risk of AI in late pregnancy. Higher education on the other hand, reduced the risk. Experiencing AI in late pregnancy was the strongest predictor of AI one year after delivery. Women with obstetric anal sphincter injury were at increased risk of flatus or stool incontinence, whereas operative delivery was associated with increased risk of urgency.

Paper II: Between 20 and 30% of the women experiencing AI in late pregnancy, reported this to affect their Quality of Life. The majority reported only a low impact on Quality of Life. Those experiencing urgency alone reported little or no impact on

Quality of Life, whereas women experiencing more than one symptom reported moderate to severe impact on Quality of Life. Compared to urgency only, women experiencing flatus alone weekly or more or women reporting a combination all AI symptoms reported the highest impact in the QoL domain “Embarrassment”.

Paper III: One in three of the 862 participants responding in late pregnancy, six and twelve months postpartum experienced AI in late pregnancy and one third of these experienced persistent symptoms six and twelve months after delivery. New onset AI was reported by 15% both at six and twelve months postpartum. AI at one year after delivery was associated with young age and AI in late pregnancy or at six months. Occiput posterior presentation was the only delivery related risk factor increasing the risk of postpartum AI.

The results from the present study confirm previous findings that AI is relatively common in late pregnancy as well as one year after delivery. Experiencing symptoms of AI in late pregnancy is the strongest predictor of AI one year after delivery, and approximately half of women incontinent in pregnancy remained incontinent one year later. Women reporting more than one symptom of AI had a poorer Quality of Life compared with those experiencing only one symptom. Further, weekly or daily incontinence of flatus was the single symptom most strongly affecting Quality of Life. These results indicate that hormonal and mechanical changes occurring during pregnancy may have more impact on postpartum AI than vaginal delivery.

1. Introduction

Proctology and the medical discipline dealing with diseases of the colon, rectum and anus, were important branches of medicine even among the ancient Egyptians. The earliest treatise completely devoted to anorectal disease was the Chester Beatty papyrus which was written around the year 1350 BC, describing afflictions like rectal prolapse and bleeding.(87) Operative proctology was also described by Hippocrates and Roman medical writers, and the anatomy of the external anal sphincter muscle was first described by Roman physicians. Ancient reports on incontinence however, are rare and mainly related to complications of perianal fistula procedures or after spinal cord injuries.(87, 128) Early reports on urinary incontinence were related to childbirth and perineal trauma, and surgical procedures for stress urinary incontinence was introduced at the end of the 19th century.(128) Anal incontinence, however, was largely believed to be due to pelvic neuropathy until the advent of anal ultrasound in the late 1980s (137), and there is evidence to suggest that the effect of surgical procedures to repair defects in the pelvic floor muscles related to anal incontinence is reduced in the long term.(28, 88, 149) For more than 6000 years, pelvic floor muscle training (PFME) has been a part of exercise programs in Chinese Taoism.(47) PFME was introduced and popularised by the American gynaecologist Kegel in 1948 (69), and the effect of PFME in the prevention and treatment of urinary incontinence have been thoroughly documented.(17) However, a recent Cochrane review concluded that the evidence to support the treatment effect of PFME for patients with anal incontinence is weak.(104)

1.1. Definition of anal incontinence

Maintenance of anal continence is a complex physiological mechanism dependent on factors such as bowel disease, bowel habits, cortical awareness, colonic motility, compliance of the rectal reservoir, anorectal sensation, the integrity of the pelvic floor muscles and sphincter apparatus, and a number of psychological factors.(30, 70, 136) In the joint report by the International Urogynecological Association (IUGA) / International Continence Society (ICS) (63) faecal (FI) and anal incontinence (AI) are defined as the involuntary loss of solid or liquid stool, and loss of stool and/or gas, respectively. Faecal urgency involves having difficulty or being unable to defer a sudden or compelling desire to defecate.

1.2 The pelvic floor: Anatomy and function

The pelvic floor refers to the structures closing the bony pelvic outlet consisting of different layers. The muscular layer, critical in pelvic organ support, is referred to as the pelvic floor muscles (PFM). The main structural component of the PFM is the levator ani muscle group consisting of four muscles; pubococcygeus, iliococcygeus, coccygeus and puborectalis (Figure 1.a).(94, 111) Muscle injury or deterioration of the levator ani muscles may result in urinary incontinence (UI), pelvic organ prolapse and anal incontinence (AI). UI and pelvic organ prolapse will not be discussed further in this thesis.

Anal continence is in large part maintained by the sphincter apparatus. The length of the anal canal is 3-4 cm, and the anal canal is surrounded by the internal (IAS) and external (EAS) anal sphincter muscles. The anal resting pressure and the closing of the anal canal at rest, is mainly maintained by the smooth IAS (75-85%) and anal cushions with some contribution from the EAS (10-25%). With sudden distension, the voluntary contraction of the striated EAS can contribute to approximately 60% of the anal canal pressure for a short period, however, the EAS is unable to sustain this activity over time (1-2 min).(111, 135, 136) In addition, an important contribution to the anal continence mechanism is the continuous muscular activity of the puborectalis muscle (PRM), maintaining the anorectal angle formed by PRMs U-shaped loop beginning at the pubic bones passing behind the rectum (Figure 1.a and 1.b).(65, 68, 75, 111, 135) With rectal fullness, the anorectal inhibitory reflex is activated by sensory stretch receptors reflex

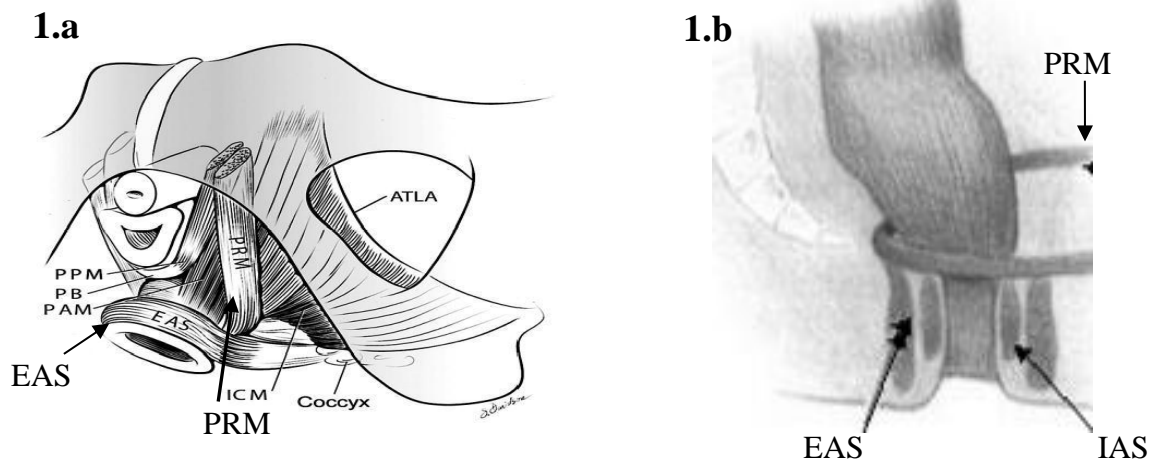


Figure 1.a: Schematic view of the levator ani muscles from below after the vulvar structures and perineal membrane have been removed showing the arcus tendineus levator ani (ATLA), external anal sphincter (EAS); puboanal muscle (PAM); perineal body (PB) uniting the two ends of the puboperineal Muscle (PPM); iliococcygeal muscle (ICM); puborectalis muscle (PRM) Reprinted with permission from Mr John O.L. DeLancey©

Figure 1.b: Lateral view of the anal canal and sphincter apparatus showing the external anal sphincter (EAS), internal anal sphincter (IAS) and the puborectalis muscle (PRM). Reprinted with permission from Janssen-Cilag AB, Sweden.

of the PRM and levator ani muscles. This reflex ensures relaxation for the IAS and descent of faecal contents into the anal canal. When socially convenient, simultaneous relaxation of the EAS and the PRM muscles allows evacuation of rectal contents. When evacuation is socially inappropriate, contraction of the EAS and PRM mediates return of the faecal contents to the rectum and re-accommodation in the colon.(136)

1.3 Anal incontinence and aetiology

The underlying pathology is unclear and AI can affect men as well as women. In a study on gender-related characteristics in patients reporting FI, men tended to have increased rectal volumes as well as higher squeeze increments, suggesting an element of anismus. Few men had anatomical or physiological abnormality of the sphincter apparatus, compared to the high proportion of women with delivery-related injuries, and FI in men was more commonly associated with history of radiotherapy and back injuries.(84) Overall however, the main aetiology is considered to be related to age, pregnancy, vaginal delivery, damage to the pudendal nerves and major tears of the perineum, PFM and obstetric anal sphincter injury (OASI) during delivery.(19, 23, 50, 51, 77, 132, 145) Hence, AI is often thought of as a woman's problem, and reports indicate that women sufferers tend to consider AI as a normal part and consequence of pregnancy as well as childbirth, and few seek medical treatment.(6, 76, 89) Findings from previous studies suggest that postpartum AI is associated with sustaining OASI during delivery (73, 74, 125, 131, 147), and it has been indicated that women with major tears including the IAS, have poorer outcomes with regards to subsequent development of incontinence symptoms.(119) Guise and co-workers (2009) found that OASI, BMI over 30 and

prolonged pushing during labour increased the odds of experiencing FI alone compared to flatus incontinence alone by 50%, 80% and 40%, respectively.(58) Twenty percent of women sustaining an OASI at delivery in Norway reported AI symptom 10 months after primary repair.(74) Since 2004, when approximately 5% of women giving birth in Norway sustained an OASI at delivery, there has been an increase in the awareness and efforts to prevent and treat these major tears of the PFM. National treatment guidelines in Norway and Great Britain recommend that women who have sustained an OASI grade 3 or 4 (137)(Table 1.1) at delivery are referred for routine follow up by Obstetricians or Colorectal Surgeons and Specialist Physiotherapists at dedicated anorectal clinics.(122, 139)

Table 1.1. Classification of perineal tears

Intact perineum	No visible tear
1 st degree tear:	Injury to skin only
2 nd degree tear:	Injury to the perineum involving perineal muscles, not the anal sphincters
3 rd degree tear:	Injury to the perineum involving the anal sphincter complex
3a:	Less than 50% EAS thickness torn
3b:	More than 50% EAS thickness torn
3c:	IAS torn
4 th degree tear:	Injury to the perineum involving the anal sphincter complex and the anal epithelium

Sultan, 1999(137)

Evaluation of sphincter function after delivery has been recommended to be performed 4-6 months postpartum at the earliest, as the spontaneous changes in pelvic floor function and reported symptoms of AI seen during the first months after delivery may be transient and thus misleading.(6, 70, 74, 100) However, there have been concerns as to whether a large number of OASI are either missed or incorrectly classified as 2nd degree perineal tears only. Andrews and co-workers found that the majority of midwives and Senior House Officers failed to diagnose an OASI when assessing

perineal tears immediately postpartum.(4) A recent systematic review of health professionals' knowledge and skills in assessing perineal tears postpartum concluded that midwives and doctors alike reported receiving inadequate training in PFM anatomy and how to diagnose perineal trauma.(97) Further, previous findings suggest that more women with FI have evidence of persistent injury of the anal sphincter complex compared to age-matched controls without FI.(14)

However, in a randomized controlled trial on the efficacy of a general exercise program including PFME in pregnancy by Stafne and co-workers (2012), performing PFME in the 2nd half of pregnancy was shown to have a protective effect among postpartum FI in multiparous however, no effect among primiparous women. These findings indicate that even among women with potential weakening or injury to the PFM or OASI from a previous pregnancy or delivery, specific training of the PFM may prevent or reduce the severity of incontinence in subsequent pregnancies.(133) Further, previous studies suggest that in the long term, injuries occurring during delivery are less important for the PFMs neuromuscular function when compared to ageing and pregnancy-related weight gain in addition to mechanical and hormonal changes.(3, 8, 23, 24, 70, 81, 101, 107, 145) Pretlove and co-workers (2008) found that mode of delivery (MoD) was only significantly associated with AI when flatus incontinence was included in the analyses, and not associated with FI alone.(113) Altman and co-workers (2007) reported faecal urgency to be less prevalent among women with caesarean section compared to vaginal deliveries.(3) Nevertheless, only minor differences have been observed in the subsequent development of FI, especially after menopause, between women with different MoDs and the long term protective benefit of caesarean deliveries compared to uncomplicated vaginal deliveries.(50, 58, 78, 101, 106, 147)

Other factors associated with AI and FI include bowel disorders, UI, neurological disorders such as stroke, Parkinson's disease and Multiple Sclerosis, Diabetes Mellitus, postmenopausal age (55-64years) and faecal urgency.(30, 118, 136) Diarrhoea as such may cause AI and FI on its own and otherwise be a strong adjunct augmenting AI and FI from any other origin. Further, AI and FI may originate from the chronic blocking effect from a rectal prolapse on the sphincter apparatus as well as an outward displacement of the linea dentata caused by anal sliding mucosal prolapse.(118, 135)

1.4 Health and Quality of Life

Traditionally, the concept of "Health" has been based on an idea of normality and in many ways a utopian state with complete *"physical, mental and social wellbeing, not merely the absence of disease and infirmity"*. (WHO,2012, p10)(46)

The primary aim of health care has been eradication of symptoms and disease, and the main health indicators have been mortality and morbidity.(46, 85) However, in recent years, there has been a shift towards a more holistic approach to health care, focusing on the patients' well-being and a modification of the complex and overall concept of "Health". The term "Health" is now more used when describing the biomedical aspects of health. The term "Quality of Life" (QoL) has been defined as *"individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"*. (WHO, 2012,p11) (46) QoL has thus been used to describe the psychological and social aspects of health as well as the subjective evaluations and the individual's perception of life in general. Subsequently, there has been an increase in the number of health

measures focusing on subjective evaluations of a person's perceived health and functional status and how disease or impairment may impact on daily activities and behaviour.

AI symptoms are often associated with embarrassment and reduction in health related QoL.(53, 82, 132) The reluctance among AI sufferers to seek medical advice or volunteer information regarding their incontinence symptoms may be due to this embarrassment as well as poor understanding and knowledge about available treatment options.(6, 30) It is recommended that both subjective and objective measurements of AI are performed, as patient-reported improvement may not be easily recognized by objective measurements alone.(21) Due to the complexity of maintaining continence, the individual perception and experience of AI may contribute more to the impact on QoL than the objective severity of AI. Boreham and co-workers (2005) suggest that incontinence frequency poorly reflects the impact of disease, among those with infrequent incontinence episodes in particular, as having experienced one or a few episodes of incontinence may lead to subsequent alterations in lifestyle in order to avoid further accidents and embarrassment.(22) Hence, it is recommended that health professionals routinely ask questions related to patients' continence status and obtain measures of condition specific Health Related QoL as well as the severity of a patient's incontinence problems.(6, 21, 22, 31, 82)

1.5 Subjective assessment and evaluation

There are a number of different scoring systems used in clinical practice for assessing frequency and severity of AI and impact on QoL, such as St. Mark's score (144),

Wexner score (67) and Fecal Incontinence Quality of Life score (FIQL).(116) However, in a review by the International Consultation on Incontinence in 2007(5), none of the reviewed assessment tools achieved the highest recommendation level (grade A) for assessment of AI. The St. Mark's score and the Wexner score were both considered to be grade C questionnaires in the early stages development in need of further investigation, whereas the FIQL score was a recommended grade B questionnaire, with some indication of validity, reliability or responsiveness established.

1.5.1 The St. Mark's score

The Wexner score and the St. Mark's score are similar, in that they both measure the frequency of AI symptoms. The main differences between the two scoring systems are that the former does not include faecal urgency, and the latter is restricted to reporting symptoms experienced in the last four weeks only.(144) Recent evaluations have shown conflicting evidence of the psychometric properties of the Wexner score, and the total and individual items of the St. Mark's score. Bakx and coworkers (2005) found that their adapted version of the St. Mark's score had insufficient reliability.(10) In a comparison of the Wexner and St. Mark's score, both including an item about flatus incontinence, and one newly developed questionnaire, the Revised Faecal Incontinence Scale (RFIS) without an item on flatus incontinence, using the last value carried forward in the analyses, the Wexner and the St. Mark's were found to be below acceptable psychometric standards.(126) Sansoni and co-workers (2013) concluded that the flatus incontinence item may be redundant and influencing the psychometric properties of the two older, and more established scores.(126) Bols and co-workers found that the item about flatus incontinence had poor external responsiveness, as

compared to the adequate responsiveness of the items regarding incontinence of formed or loose stool (FI).(18) The total St. Mark's score and the four individual items related to frequency of AI symptoms and urgency, however, were found to have excellent or adequate test-retest reliability.(20) The review also indicated that the items regarding adjustment of lifestyle, use of pads, and constipating medication may be measuring a different concept than the other items on the St. Mark's score, and thus function as markers associated with the patients' self-confidence rather than severity of AI.(20) Sansoni and co-workers (2013) on the other hand, found that 7 points or more on the RFIS warranted the use of incontinence pads.(126) Most of these evaluations have been on patients with longstanding or severe AI or FI, and thus the findings may not apply to other patient groups. Findings in a study by Maeda and co-workers (2007), however, concluded that the St. Mark's score was reliable regardless of AI symptoms experienced, age or gender.(84) Further, the St. Mark's score was recommended for use in assessing severity of AI among young healthy women following OASI as it showed a significant correlation to QoL even in a population with low severity.(120)

1.5.2 The Fecal Incontinence Quality of Life scale

The FIQL was developed to evaluate health-related QoL in patients with symptomatic AI and is widely used in clinical practice. It considers the four QoL domains "Lifestyle", "Depression", "Coping Behaviour" and "Embarrassment".(116) The FIQL consists of 29 items and has been criticised for not being user-friendly, including too many and overlapping items, no weighting of individual items, and including only three items in the "Embarrassment" domain.(38, 62, 108, 142) The Norwegian version of the FIQL score has recently been validated and the internal consistency, test-retest

reliability and construct validity of the FIQL scale were all found to be adequate (38), confirming the significant correlation previously demonstrated between the four FIQL domains as well as with the St. Mark's score.(18) Further, Kwon and co-workers found that the self-administered FIQL scale was significantly correlated with the telephone-administered Manchester Health Questionnaire.(71)

1.5.3 Symptom severity and Quality of Life

There has been some debate as to whether symptom severity is associated with QoL, or if other factors such as age and duration also influences QoL measures.(21, 49, 61, 121, 130) Experiencing AI symptoms postpartum has been reported to affect QoL only mildly (109), and one study reported a Wexner score of 9 points or more indicated a significant reduction in a patient's QoL.(121) In a study comparing patient and surgeon ranking of AI symptom severity and QoL (117), the rankings were similar and highly correlated except for the severity of incontinence of solid stool. The surgeons tended to emphasize physiological events such as solid stool incontinence more than patients who emphasized symptoms affecting personal hygiene and potential embarrassment such as incontinence of flatus and mucus. Further, reductions in three FIQL domains "Lifestyle", "Coping" and "Embarrassment" correlated well with increasing Wexner scores.(117)

1.6 Objective assessment and evaluation

Endoanal ultrasound and digital palpation are most commonly used to examine the extent of perineal damage and the ability to actively contract the sphincter muscles and other pelvic floor muscles, respectively.(136) Anal manometry is the most frequently

used method to measure and quantify sphincter and pelvic floor muscle strength.(15, 16) However, there has been some debate on the correlation between the patients' continence status and the manometry measurements, due to the numerous factors contributing to the maintenance of continence and the relatively large individual differences in normal values of pressure measurements of the anal sphincter muscles.(44) Anal electromyography (EMG) measures muscle activity of the sphincter and pelvic floor muscles, and is widely used as basis for biofeedback in PFME treatment of AI.(104)

1.7 Prevalence of anal incontinence

Due to the socially debilitating consequences of AI, symptoms may be under-reported, and there is reason to believe that as few as 20-30% of sufferers seek medical care.(6, 30, 80) Further, the reported prevalence of AI varies markedly in the literature, mainly due to differences in populations studied, timing of questions, measuring tools used and definitions of AI and FI.(58, 77)

1.7.1 Anal incontinence in the general population

In the general population, the prevalence of FI experienced during the last 12 months was found to be between 2-4%, and more common in women than men.(81) In a more recent study from New Zealand (129), 12.4% reported experiencing leakage of formed or loose stool 1 to 3 times per month. In a systematic review, Pretlove and co-workers (2006) found that FI increased with age, and that 0.8% and 1.6% of men and women, respectively, aged under 60 experienced FI, whereas in older men and women, the

prevalence was 5.1% in men and 6.2 % in women.(114) In the elderly, and nursing home residents, AI affects men and women equally.(123, 135)

1.7.2 Anal incontinence in the female population

In the female population however, results from a recent study show that nearly 20% of American women over the age of 45 had experienced one or more episodes of FI in the past year and 97% reported to be bothered by this.(30) One in five women in Norway over the age of 30 reported experiencing symptoms of AI during the last month.(118) Even though AI has been shown to increase with age and parity in women, there is a tendency towards a double peak incidence in AI related to obstetric trauma, with AI being more common among young and middle-aged and post-menopausal women.(1, 81, 92, 102, 115, 118, 131, 136) Further, previous findings indicate that the majority of multiparous women with AI symptom, report the onset of their symptoms in relation to the delivery of their first or second child, and many women experience changes in their continence status and reductions in quality of life upon return to work after maternity leave.(59, 81, 86)

1.7.3 Anal incontinence in pregnancy and postpartum

In pregnancy, the reported prevalence of AI varies between 3% and 65% (35, 51, 70, 73, 99, 132, 133, 141, 145), whereas between 4% and 49% report AI in the first year postpartum (13, 23, 35, 37, 59, 70, 90, 110, 132, 141, 145) In the study by Torrisi and co-workers, 33% experienced new onset AI symptoms during pregnancy and 39% postpartum.(141) This is similar to the 45% of primiparous women reporting new onset of at least one AI symptom at any frequency 3-6 months after the delivery of their first child in the study by Guise and co-workers (2009). In these women, nearly half reported

new onset of at least one AI symptom, and one in five were incontinent of loose stool. One in three reported faecal urgency, whereas only 3% reported urgency alone as their only symptom.(58) The prevalence of postpartum AI was slightly higher, though not significantly different for women with vaginal delivery compared to caesarean delivery. In the study by van Brummen and co-workers (2006) approximately 50% of women who were incontinent in pregnancy, reported persistent symptoms one year after delivery, whereas new onset of stool and flatus incontinence one year after delivery was reported by 2.6% and 8.5%, respectively.(145)

In the long term, 5-10 years after index delivery, the prevalence of FI and AI varies between four and 26% (3, 77, 79, 102, 127) and 12 and 35% (60, 112), respectively. Risk factors for increased severity of FI include episodes of FI occurring more than monthly, being overweight ($\text{BMI} \geq 30$), prolonged 2nd stage of labour, urgency, urinary incontinence and bowel disorders.(30, 58)

2. Study aims

The overall study aim was to evaluate the prevalence and predictors of anal incontinence among first time mothers and explore the impact of anal incontinence in health-related quality of life in late pregnancy and the first year after delivery.

More specifically, the aims of the separate papers were:

2.1 Study aims paper I

-To evaluate the prevalence and predictors of the specific symptoms of anal incontinence, including urgency, in late pregnancy and one year after delivery.

2.2 Study aims paper II

-To explore how experiencing different types of anal incontinence in late pregnancy affects health-related quality of life among primiparous women.

2.3 Study aims paper III

-To explore the changes in continence status from late pregnancy and throughout the first year postpartum among healthy primiparae. The secondary aim was to investigate factors associated with persistent and new onset AI symptoms twelve months postpartum.

3. Methods and material

3.1 Study design

All data presented in the three papers of this thesis were collected in a prospective cohort study conducted in the period between May 2009 and April 2011 at Ostfold Hospital Trust Fredrikstad and St. Olavs Hospital/ Trondheim University Hospital. The designs of the three separate papers are summarised in Table 3.1.

Table 3.1 Study designs

Paper	Theme	Design
I	Prevalence and predictors of AI in LP and 1yPP	Prospective cohort
II	AI and QoL in LP	Cross-sectional
III	Changes in continence status from LP and during the first year postpartum, and the association between continence status in LP and 6moPP, and experiencing AI 1yPP	Prospective cohort

3.2 Study population

Norwegian speaking primiparae over the age of 18 giving birth to healthy infants in the two hospital sites were consecutively invited to participate in the study. Exclusion criteria were age under 18, and inadequate Norwegian, as the questionnaires were available in Norwegian only. Women with poor physical or mental health after delivery, delivering very poorly infants or infants requiring prolonged admission to the paediatric intensive care unit, were approached only when advised by medical staff at the maternity wards. The inclusion period was from May 2009 to December 2010 and the data collection was completed in April 2011. The study participants in the three papers are described in Table 3.2 and in Figure 4.1.

Unfortunately, due to difficulties with logistics, and the physiotherapists including participants to the study only being available during the normal working week, we were unable to record the exact response rate and reasons for non-participation for primiparae not included in the study.

Table 3.2 Study participants

Paper	Theme	Participants
I	Prevalence and predictors of AI in LP and 1yPP	Primiparae giving birth in the inclusion period
II	AI and QoL in LP	Primiparae reporting symptoms of AI in LP
III	Changes in continence status from LP and during the first year postpartum, and the association between continence status in LP and 6moPP, and experiencing AI 1yPP	Primiparae responding at all three time points; LP, 6moPP and 1yPP

3.3 Data collection

Shortly after delivery, primiparae in both hospitals were contacted by a physiotherapist and asked to complete a self-reporting questionnaire concerning AI symptoms (St. Mark's score) and health related Quality of Life (FIQL) experienced during the last four weeks of pregnancy. Completed questionnaires were returned in designated mail boxes at the maternity wards. Women, who did not return the questionnaires before discharge from the maternity wards, received a reminding postal questionnaire to be returned in mailed pre-stamped return envelopes. Six and twelve months after delivery the participants received postal questionnaires with mailed pre-stamped return envelopes. Non-responders received postal reminders after four weeks.

At Ostfold Hospital Trust, the background data were collected directly from the electronic data base PARTUS[®], version 3.6.1 (CSAM Health AS, Lysaker, Norway;

Version 3.6.1), whereas the background data was collected from the participants' medical hospital records at St. Olavs Hospital.

3.4 Methods

The primary outcome variable in all three papers included in this thesis was self-reported AI symptoms using the St. Mark's score. In addition, the secondary outcome variable was self-reported health-related QoL as reported on the FIQL score in **paper II**, as summarized in Table 3.3.

Table 3.3 Questionnaires used

Paper	Theme	Questionnaires
I	Prevalence and predictors of AI in LP and 1yPP	St. Mark's score in LP and 1yPP Background data, including delivery related data
II	AI and QoL in LP	St. Mark's score in LP FIQL domains in LP Background data, excluding delivery related data
III	Changes in continence status in LP and the first year postpartum, and association between continence status and experiencing AI 1yPP	St. Mark's score in LP, 6moPP and 1yPP Background data, including delivery related data

3.5 St. Mark's score

On the St. Mark's score, the frequency of leakage of formed and loose stool, gas and alteration of lifestyle are measured on a five point scale (never, rarely, sometimes, weekly and daily). St. Mark's score also includes three questions with dichotomous scales regarding the use of pads, constipating medicine (no= 0, yes =2 points) and the ability to defer defecation for 15 minutes (no = 4, yes = 0 points) (Appendix St. Mark's score). The total St. Mark's score ranges from complete continence (0 points) to complete incontinence (24 points). Faecal urgency has previously been shown to have a

strong association with leakage of stool or gas.(93, 118). As the St. Mark's score measures the frequency of AI symptoms during the last four weeks prior to completing the questionnaire only, this scoring system was chosen as symptoms experienced during the specific time periods in late pregnancy, and 1yPP were the focus in the present study. As the primary aim of the three papers in this thesis was to evaluate AI symptoms and combinations of symptoms, we thus decided to report on specific items derived from the previously validated St. Mark's score (**Paper I and II**), rather than on the total St. Mark's score. In **paper III**, the participants were categorized into continent (no AI symptoms) or incontinent (one or more AI symptoms reported as according to the definition of AI in the present thesis). Subsequently, in this study, AI has been defined as experiencing one or more of the following symptoms; leakage of formed or loose stool monthly or more, leakage of flatus weekly or more, or the inability to defer defecation for more than 15 minutes.

3.6 Fecal Incontinence Quality of Life scale

There is no total FIQL score, however the scale is subdivided into the mean of all items included in the respective four domains; "Lifestyle" (10 items), "Coping/ Behaviour" (9 items), "Depression/ Self-Perception" (7 items) and "Embarrassment" (3 items). In total, 27 of the 29 items were rated on a 4-point scale, one item on a 5 point scale (Question 1) and one item on a 6 point scale (Question 4), and a lower score indicating poorer quality of life (Appendix FIQL). As the FIQL was recommended by Avery and co-workers (2007) (5) and already implemented in clinical practice in the participating hospitals, the FIQL scale was chosen as the QoL assessment tool in this study. In **paper**

II, QoL was defined as “reduced” when the mean score was below 3.8 points in the FIQL domains and otherwise “not reduced”. As the FIQL is a condition specific questionnaire, FIQL scores were analysed for women reporting AI symptoms only.

3.7 Background data

In all three papers in this thesis, demographic data such as age, marital status, work status at start of pregnancy, BMI in late pregnancy and highest educational level completed were included in the statistical analyses. In **papers I and III**, delivery-related data such as birth weight, MoD, presentation of the foetal head, grade of perineal tear, use of epidural and episiotomy were also included in the statistical analyses. In **paper II**, the primary focus was AI symptoms and QoL experienced prior to delivery and delivery related data were not included in the statistical analyses.

3.8 Power calculation

This study is part of a larger project aimed at exploring both the prevalence and predictors of AI and QoL in late pregnancy and the first year postpartum, as well as a randomised controlled trial (RCT) investigating the effect of PFME among women with symptoms of AI postpartum, but without known OASI. The primary aim of this entire project was to evaluate self-reported AI symptoms as reported on the St. Mark’s score. The sample size of the population on which the studies presented in the three papers was based on, was the sample size needed in the RCT. The primary outcome in the RCT was percentage of participants reporting reduction in AI symptoms 6 months

postpartum. Based on similar studies and clinical experience, we expected reductions in AI symptoms in 50% of participants in the intervention group and 20% in the control group after six months of PFME treatment. The chosen significance level was 5%. The sample size required to have an 80 percent chance of detecting a significant difference between the two groups, was then found to be 72, i.e. 36 participants in each group. The expected loss to follow-up was 5-10% and thus the aim was to recruit 80 participants in the RCT and 1500 in the prevalence study.

3.9 Statistical analyses

3.9.1 Missing data

As the mean percentage of missing values in single items of the completed questionnaires was as low as 1.2%, the following simple imputation procedure was used: missing values of a single item were replaced by the mean of the item scores on the completed St. Mark's score (**papers I, II and III**) and FIQL questionnaires (**paper II**). The mean percentage of missing values of the demographic and delivery-related background data collected was 3.9%. The missing values on these variables were not imputed.

3.9.2 Categorisation and group comparison

The categorisation of participants in the three papers is summarised in Table 3.4. In **paper II**, more than 60 % of the women who experienced at least one AI symptom reported no impact on QoL. FIQL domains were therefore dichotomised into “reduced” and “not reduced”, and analysed as categorical variables using logistic regression

analyses. In **paper III**, the participants were categorized into “continent” or “incontinent” (Table 3.4).

Prevalences with 95% confidence intervals were calculated for the AI outcome variables in each of the three papers. Comparison between two groups of participants specified was performed, as described in Table 3.4. The independent samples t-test was used to compare means in two groups, and the chi square test or the Mann Whitney U tests were used when comparing categorical data in two groups. In **paper I**, the McNemar test was used when comparing categorical variables in LP and 1yPP. A significance level of 5% was chosen for all three papers.

Table 3.4 Categorisation and group comparison in statistical analyses

Paper	AI group categories	Group allocation for statistical analyses
I	Incontinence of formed stool Incontinence of loose stool Incontinence of flatus Faecal urgency	<ul style="list-style-type: none"> • Participants responding both in late pregnancy and 1yPP • Participants responding in late pregnancy only
II	Urgency only Stool only (formed and/or loose stool) Flatus only Stool and urgency Stool and flatus Urgency and flatus All symptoms	<ul style="list-style-type: none"> • Participants experiencing AI symptoms in late pregnancy • Participants not experiencing AI symptoms in late pregnancy
III	Continent Incontinent	<ul style="list-style-type: none"> • Participants continent or incontinent in LP • Participants continent or incontinent 6moPP • Participants continent or incontinent 1yPP

3.9.3 Univariate and multivariate logistic regression analyses

In **paper I**, the univariate associations between the AI symptoms as dependent variables and the various independent aetiological variables, such as age, BMI at delivery, and mode of delivery, were assessed using the chi square test (Table 3.5).

In **paper II**, the univariate associations between the various dichotomised AI symptoms and the four dichotomised QoL domains were assessed using the chi square test (Table 3.5). In **paper III**, the univariate associations between AI 1yPP as dependent variable and the background and delivery related data as independent variables, were assessed using the chi square test (Table 3.5). For **papers I and II**, the background variables found to be significantly related to the dependent variables AI symptoms (**paper I**) and FIQL domain (**paper II**) using the chi square test, were included in separate univariate logistic regression analyses. In **paper III** the variables found to have an association with the primary outcome variable AI at 1yPP, with a p-value lower than .20, were included in a univariate logistic regression analyses. Variables found to be significantly associated with the dependent variables in the univariate analyses in **papers I and II** were included in multivariate logistic regression models together with potential confounding variables. In **paper III**, the variables found to have an association with the primary outcome variable with a p-value lower than .20 in the univariate logistic regression analyses, were included in a multivariate logistic regression model with backward variable selection (Table 3.5). The multivariate regression analyses were conducted to evaluate the independent strength of the association between the dependent and independent factors chosen in each paper. None of the variables in the multivariate logistic regression models of the three papers were highly correlated

(Spearman's correlation above 0.70 or below -0.70), thus the multivariate regression analyses were not invalidated by collinearity. All statistical analyses were performed using SPSS for Windows version 18 (Statistical Package for Social Sciences, SPSS Inc., Chicago IL, USA).

Table 3.5 Univariate and multivariate regression analyses

Paper	Dependent variables	Independent variables	Variables included in the multivariate analyses
I	AI symptom categories	Background variables	<ul style="list-style-type: none"> • Age • Education level • Work status • BMI in LP • OASI
II	FIQL domain scores	AI symptom categories	<ul style="list-style-type: none"> • Age • Education level • Work status • BMI in LP • Constipating medicine
III	AI 1yPP	Background variables	<ul style="list-style-type: none"> • Age • Education level • BMI in LP

3.10 Ethics

Participants received written or verbal information about the project and written consent was obtained prior to inclusion in the study, as in accordance with the Declaration of Helsinki. The study was approved by the Norwegian Regional Committees for Medical and Health Research Ethics (REC Central, No ((6)2008.1318) and the Norwegian Social Science Data Services (NSD) before data collection was commenced. The study is registered at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00970320) (NCT00970320).

4. Results

4.1 Main results

A total of 1571 primiparae consented to participate in the study. In the recruitment period, there were 3442 deliveries by primiparous women at the two hospitals. Between 5% and 10% of these women were not eligible for participation and the overall response rate was approximately 50%. A total of 1069 and 1031 women responded at 6moPP and 1yPP, respectively, (Figure 4.1) and 862 women responded at all three time points (Figure 4.2).

4.2 Summary of paper I

Prevalence and predictors of anal incontinence during pregnancy and one year after delivery. A prospective cohort study.

Hege Hølmo Johannessen, Arne Wibe, Arvid Stordahl, Leiv Sandvik, Bjørn Backe, Siv Mørkved

The primary aims of this study were to evaluate prevalence and predictors of anal incontinence in late pregnancy and one year after delivery among primiparous women. A total of 1571 women responded in late pregnancy and 1031 one year later. At least one AI symptom was experienced by 24% and 19% in late pregnancy and one year after delivery, respectively. Faecal urgency was the most frequently reported symptom at both time points. Three or more AI symptoms were experienced by 4.7% in late pregnancy and 2.2% one year later. Multiple logistic regression analyses showed that incontinence of formed and loose stool incontinence was strongly associated at both baseline and one year later. Incontinence of formed or loose stool was also closely related to urgency. Predictors of AI one year postpartum tended to be delivery-related;

however the main predictor of experiencing any AI symptom one year postpartum was experiencing the same AI symptom in late pregnancy. The aetiologies of the different symptoms of AI appeared to be different, as incontinence of stool and/ or flatus one year after delivery were all significantly associated with OASI at delivery, whereas urgency was significantly associated with operative deliveries and higher age at delivery, and not OASI. We conclude that AI appears to be a common problem among primiparous women both in late pregnancy and one year postpartum. Our findings support the ongoing initiative to prevent unnecessary damage to the pelvic floor during delivery, and suggest that identifying women experiencing AI in late pregnancy and those with OASI may aid facilitation of adequate treatment and follow-up postpartum.

4.3 Summary of paper II

Anal incontinence and Quality of Life in late pregnancy: A cross-sectional study.

Hege Hølmo Johannessen, Siv Mørkved, Arvid Stordahl, Leiv Sandvik, Arne Wibe

The primary aim of this study was to evaluate the association between the different types of anal incontinence and Quality of Life in late pregnancy. Thirty-six percent (573) of the 1571 included women experienced AI symptoms in late pregnancy. Women experiencing urgency alone reported a markedly better QoL compared to women experiencing all other symptoms or combination of AI symptoms. One in four and one in five of the women experiencing AI symptoms reported AI to affect the FIQL domains “Coping” and “Embarrassment”, respectively. Also in the multiple logistic regression analyses, AI appeared to have a stronger impact on the domains “Coping” and “Embarrassment” than the other two FIQL domains. Those experiencing incontinence of flatus alone found this symptom to be highly embarrassing, and

reported the highest impact on any QoL domain compared to women experiencing any type of AI symptoms, except those experiencing the combination of all AI symptoms. The independent association between all four FIQL domains was strong, with the association between the domains “Depression” and “Lifestyle” being particularly strong. These findings suggest that the complexity of maintaining continence and the embarrassment/stigma associated with being unable to control one’s bowels, may result in AI affecting several QoL domains, “Depression” in particular, if experiencing more than one AI symptom. We conclude that 3-10% of the women experiencing AI in late pregnancy, also reported AI to affect their QoL. The greatest impact was seen in the domain “Coping”, closely followed by the domain “Embarrassment”. These findings highlight the importance of an increased awareness on AI in late pregnancy among health professionals, and the need to implement routine discussions about AI with expectant and new mothers.

4.4 Summary of paper III

Changes in anal incontinence among first time mothers- what happens in pregnancy and the first year after delivery?

Hege Hølmo Johannessen, Arne Wibe, Arvid Stordahl, Leiv Sandvik, Siv Mørkved.

The aims of this study were to explore changes in continence status from late pregnancy and during the first year after delivery among primiparae, and to investigate factors associated with experiencing AI symptoms twelve months postpartum.

This cohort study included the 862 primiparae who responded to all three time points; late pregnancy, 6mpp and 1yPP. Interestingly, more women were incontinent in late

pregnancy than after delivery, as 292 (34%) reported AI in late pregnancy, whereas 186 (22%) and 199 (23%) were incontinent 6moPP and 1yPP, respectively. Among women incontinent during pregnancy, 105 were incontinent at 6moPP and 114 at 1yPP. Ninety-nine women incontinent at 6moPP also experienced persistent AI at 1yPP. New onset AI was reported by 81 (14%) and 85 (15%) at 6moPP and 1yPP, respectively. Young age and AI in late pregnancy or 6moPP were risk factors for reporting AI at 1yPP. Occiput posterior presentation was the only delivery related variable increasing the risk of postpartum AI (OR:1.6, 95% CI:1.0-2.7). The present results support the view that hormonal changes and mechanical trauma in late pregnancy may be likely to induce functional impairment to pelvic organs than earlier recognized. We conclude that one in three women suffered AI during late pregnancy and one third of these experienced persistent AI during the following year. New onset AI was reported by 15% at both time points postpartum and more than half of women incontinent at 6moPP experienced persistent AI six months later. Experiencing AI symptoms 1yPP was associated with AI in late pregnancy or 6moPP, and the results may indicate that hormonal and mechanical changes in pregnancy may affect postpartum AI more than vaginal delivery. Considering that only one in five volunteer information or seek medical help for their AI symptoms, mainly due to embarrassment, there is a need for an increased awareness among health professionals about the prevalence and predictors of experiencing AI symptoms in pregnancy and postpartum. Further, health professionals should inform pregnant and postpartum women about AI symptoms, e.g. that they are common and may be transient

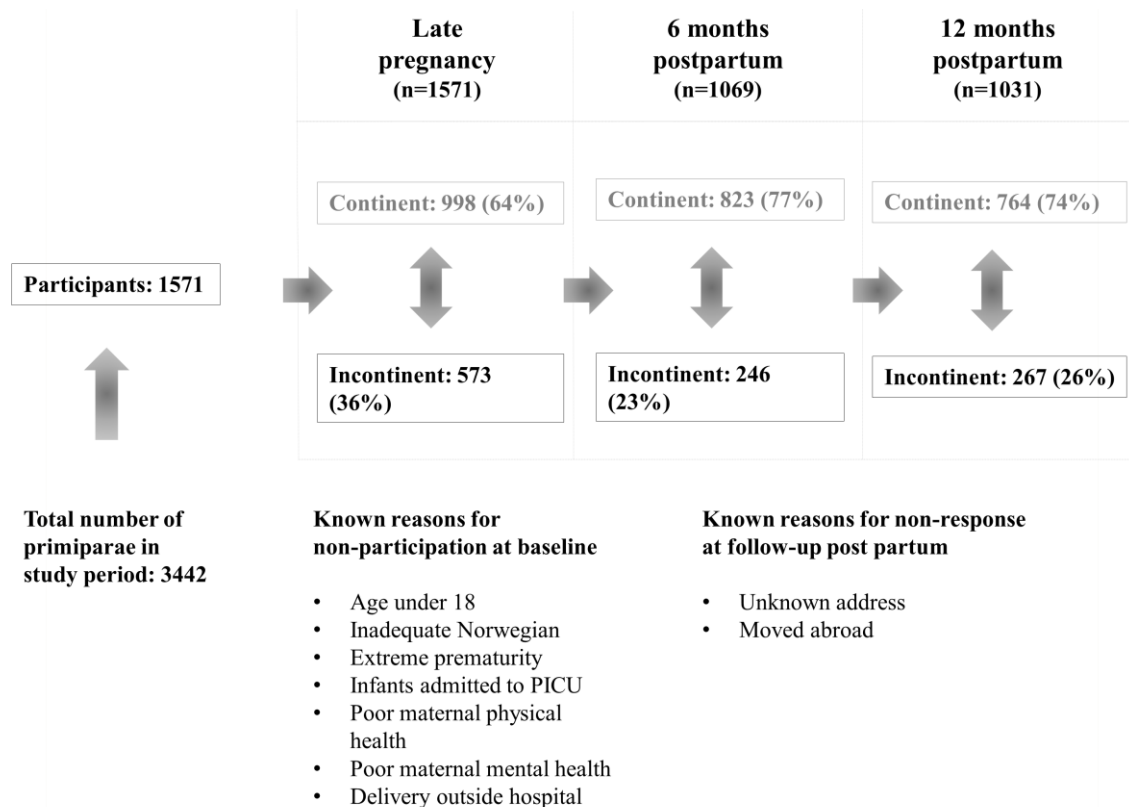


Figure 4.1. Studyparticipant flow chart

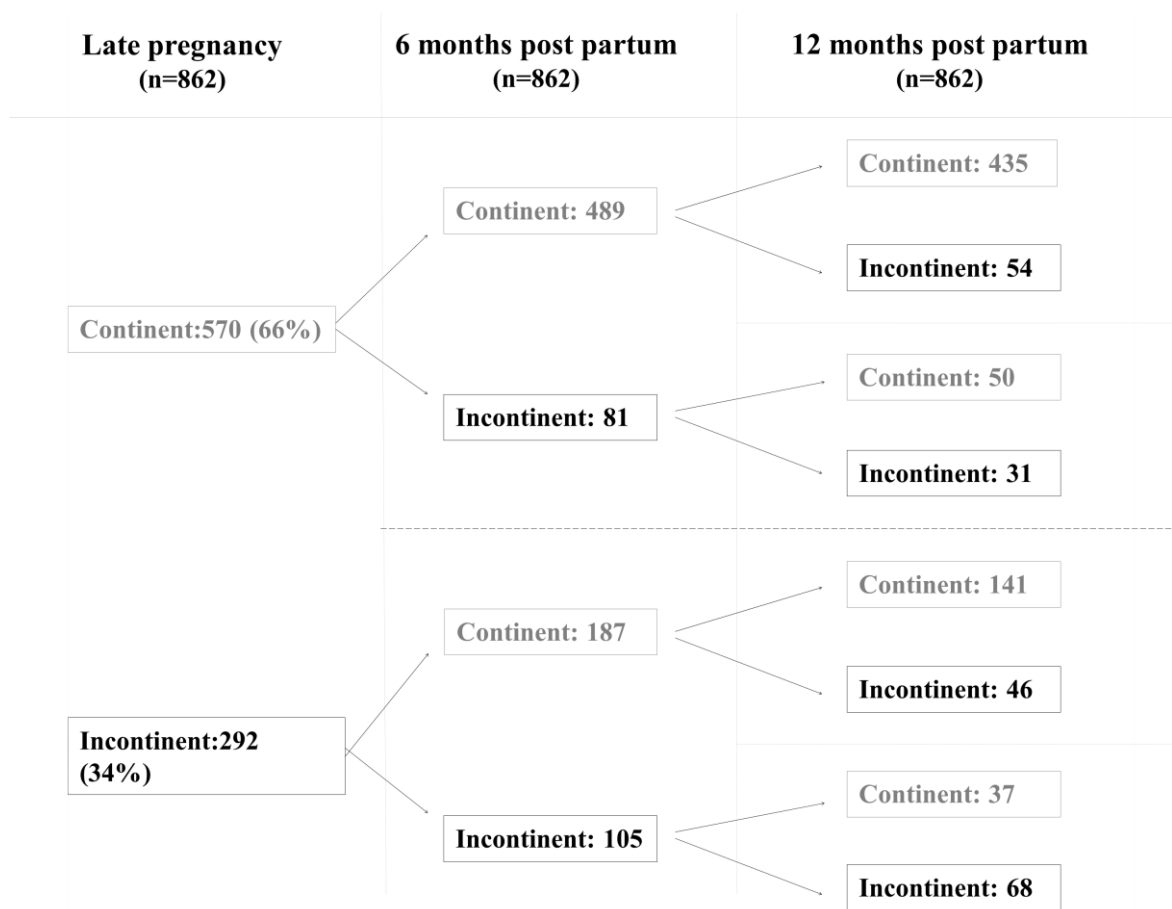


Figure 4.2. Participants responding at all three time points; LP, 6moPP and 1yPP

5. Discussion

5.1 Main findings

5.1.1 Prevalence of anal incontinence

In the present thesis, AI was found to be a common problem among primiparae, both in late pregnancy, 6moPP and 1yPP. One third among both the 1571 included primiparae in **Paper I**, and 862 primiparous women responding at all three time points in **Paper III** experienced at least one AI symptom in late pregnancy. One in five reported AI at 6moPP and 1yPP. In the literature the reported point prevalence of AI in pregnancy and postpartum varies markedly, and is reported to be both lower (13, 35, 102, 115) and higher (32, 59, 132) than the prevalence found in the present study. These discrepancies in prevalence may be due to different definitions of AI, FI and the definition and inclusion/exclusion of flatus incontinence in particular, as well as the timing of questions, population studied and whether the prevalence is explored during pregnancy or in the short or long term postpartum. In a study on AI among pregnant women, Laine and co-workers (2013) found that nearly 8% of the nulliparous women reported AI, defined as 3 points or more on the St. Mark's score.(73) In comparison, the mean St. Mark's score among the 292 (34%) women incontinent at 1yPP in **paper III** (Table 1) was found to be 3.8 points, 3.4 points and 4.9 points in late pregnancy, 6moPP and 1yPP, respectively. In the present thesis, flatus incontinence was defined as reporting weekly leakage or more, as opposed to flatus incontinence at any frequency reported in many studies.(29, 32, 70, 145) One third of the women reporting flatus incontinence six months after delivery in a previous study, experienced symptoms weekly or more often, whereas one in five reported daily leakage of flatus.(23) In **paper I**, however, 6% reported flatus incontinence weekly or more 1yPP.

Few studies have reported on faecal urgency as a separate symptom, however, in the present study, it was the most frequently reported symptom in late pregnancy as well as postpartum. A total of 20% reported urgency and problems deferring defecation one year after delivery (**paper I**), which is slightly higher than reported in the study by Brown and co-workers (2012) (32), and slightly lower than reported at six months postpartum by Borello-France and co-workers (2006).(23) The prevalence of urgency in the present study is more than twice as high as reported by Chaliha and co-workers (2001).(35) However, in their study the prevalence reported was referring to problems deferring defecation for 5 minutes and not 15 minute as reported in the present study. Nelson and co-workers (2006) found urgency to be less prevalent among both primi- and multiparous women following caesarean section when compared to vaginal delivery.(101)

The prevalence of new onset AI at six and twelve months postpartum (**paper III**) was lower than previously documented in the literature. New onset AI or FI among primiparae has been reported by 6-18% at three months postpartum (35, 36), 45% to 73% at six months postpartum (23, 32), and 20-28% three to four years postpartum.(127) Interestingly, fewer women developed new onset AI postpartum, compared to women experiencing AI persisting from pregnancy to the postpartum period (**paper III**). These results may thus challenge the opinion that vaginal delivery is the main cause of women's anal incontinence. In a South African study, the overall prevalence of AI was reduced between six weeks and six months postpartum and persistence of stool incontinence was reported to be higher among primiparae, as compared to multiparae.(99) Persistent AI 1yPP was in the present study reported by 39% and 53% of the women incontinent in late pregnancy and 6moPP, respectively. This is similar to the results in a study by Brown and co-workers (2012). However, the prevalence of new onset AI between four and twelve months partum reported by Brown and co-workers (2012) was as high as 73% among women continent in the first three months postpartum .(32) Torrisi

and co-workers (2012) on the other hand, reported the prevalence of persistent (33%) and new onset AI symptoms (39%) to be similar at three months postpartum (141), whereas Chaliha and co-workers (1999) reported that 17% experienced persistent symptoms at three months postpartum.(36)

5.1.2 Predictors of anal incontinence in late pregnancy and postpartum

5.1.2.1 Socio-demographic factors

Results from a study by Brown and co-workers (2012) suggest that women aged 35 years or more at delivery have increased odds of postpartum FI.(32) In contrast, women aged 35 year or more in the present study (**paper I**) were at increased risk of urgency only, whereas women younger than 23 years at delivery were found to have significantly increased risk of FI in pregnancy and loose stool incontinence one year later (**paper I**). Furthermore, young mothers had a significantly higher risk of AI at 12 months regardless of continence status in late pregnancy and 6moPP (**paper III**), supporting the results in a South African study reporting a significantly higher incidence of new onset FI among women younger than 20 years at first delivery.(99) High education was in the present study shown to reduce the risk of AI in late pregnancy (**paper I**). In a recent Norwegian study, Laine and co-workers (2013) found low educational level to be significantly associated with experiencing AI symptoms among pregnant nulliparous women.(73) In **paper I**, unemployment was found to increase the risk of experiencing all symptoms of AI in late pregnancy. One year later however, unemployment was only associated with experiencing urgency (**paper I**). Furthermore, the findings in **paper I** confirmed previous reports on the association between AI and high pre-pregnancy and pre-delivery BMI.(33, 58) Burgio and co-workers (2007) only found this association in women sustaining an OASI at delivery, and not in women with uncomplicated vaginal delivery or caesarean section.(33) The increased intra-abdominal pressure found to be associated with

obesity (9) may result in a weakening of the PFM and thus mediate the development of postpartum AI. In **paper III**, however, we found no association between being incontinent at twelve months postpartum and any socio-demographic factors, except young age at delivery. This may to some extent be explained by the somewhat coarser categorisation of AI into “incontinent” and “continent”, as compared to the four separate AI symptom-categories used in **paper I**. The results from **paper I** indicate a possible difference in aetiology between urgency and incontinence of stool or flatus.

Overall however, the main independent predictors of experiencing any AI symptom one year after delivery were experiencing AI in either late pregnancy or 6moPP (**paper I and III**). This is in concurrence with similar studies.(102, 131, 132, 145) It has also been suggested that new onset AI symptoms nine months after delivery and increasing number of childbirths is a significant risk factor of persistent AI 5-10 years postpartum.(79, 102, 112) Moreover, persistent AI in the long term has previously been reported to be associated with more adverse general health compared to non-persistent AI.(79)

The data collected in the present study included no information regarding neither family history of AI, nor if the participants had experienced AI prior to or early in their first pregnancy and the possible impact on QoL. These are factors previously recognized as predictors of AI in late pregnancy as well as postpartum (32, 141), and may have influenced the results of the present study. Further, data on the prevalence of UI was not included, as it was considered to be beyond the scope of this thesis. However, Burgio and co-workers found the presence of antenatal UI to predict postpartum FI as well as UI at 6 months postpartum (33), and an increased prevalence of FI among women with UI compared to women continent of urine has previously been reported.(48, 51, 112, 137) Moreover, the background data collected in the present study did not include information on the prevalence of the potentially

confounding condition diarrhoea. However, only a very limited number of participants were found to be diagnosed with conditions associated with diarrhoea such as Ulcerative Colitis or Crohn's Disease (data not shown). It was thus considered unlikely that diarrhoea had more than a minor influence on the results in the present thesis.

5.1.2.2 Delivery related factors

Some authors report no association between MoD and subsequent development of FI 3 to 4 years after delivery (127) or AI in the long term.(118) However, previous reports show that approximately 50% of women lose some of the supporting function of the pelvic floor due to childbirth (138), and results from recent research using ultrasound and MRI indicate a prevalence of major injuries to the PFM between 20-26% % following vaginal delivery (39, 40, 45) The predictors of any AI symptom one year after delivery identified in **paper I**, tended to be delivery-related, except experiencing AI in late pregnancy. Similar to a previous report (48), sustaining an OASI at delivery increased the risk of postpartum stool (FI) and flatus incontinence, but not urgency (**paper I**). Increased risk of urgency, on the other hand, was associated with operative delivery, high age at delivery, and unemployment (**paper I**). Pretlove and co-workers (2008) found MoD to be associated with AI and not FI alone (113) and Chaliha and co-workers (1999) identified operative delivery as an independent risk factor for postpartum AI and faecal urgency, when compared to caesarean delivery.(36) Furthermore, Badiou and co-workers (2010) found both OASI and operative deliveries to be significantly associated with FI and altered continence status 15 months postpartum. They found no association however, between the only delivery-related risk factor identified in **paper III**, occiput posterior position and AI.(7) Malposition of the foetus at delivery, such as occiput posterior position, has been shown to be associated with an increased risk of operative delivery (98), and operative deliveries have been found to increase the risk of OASI.(48, 92) Some authors argue, however, that operative delivery is one of several markers of a

complicated delivery, rather than an independent risk factor for AI (48, 92), and thus an indirect risk factor of postpartum AI. As compared to vacuum deliveries, operative deliveries using forceps or vacuum and forceps combined have been reported to increase the risk of altered continence status and anal sphincter defects.(55, 58, 98, 134) The majority of women with an operative vaginal delivery in the present study had a vacuum delivery (253/272) and only a total of 19 women had a failed vacuum delivery resulting in a forceps delivery, or forceps delivery alone (Table 1, **paper I**). We were thus unable to explore the association between forceps deliveries and AI.

5.1.2.3. Caesarean delivery

In a systematic review exploring the role of caesarean section and preservation of anal continence, Nelson and co-workers (2006) found that 167 caesarean sections would have to be performed to prevent one single case of FI, and 402 in order to prevent flatus incontinence.(101) These findings are in concurrence with previous reports of caesarean deliveries, showing no protective effect with regards to development of FI symptoms three to six months postpartum.(58) However, in a study by Wegnelius & Hammarstrøm (2011), one third of the primiparae who had sustained an OASI at the first delivery, wanted to postpone or abandon further deliveries, and 49% delivered by caesarean at their next delivery, mainly due to AI or complications following the OASI.(147) The present study show no statistically significant difference in the association between vaginal delivery, or caesarean section with regards to experiencing any AI symptom one year postpartum (**paper I** and **III**).

5.1.2.4 Obstetric anal sphincter injury

Laine and co-workers (2013) found OASI to be a significant risk factor for AI in multiparous pregnant women only.(73) Wegnelius & Hammarstrøm (2011) found that women delivering by caesarean section had more than 20 times higher odds of sustaining an OASI in subsequent vaginal deliveries compared to women with normal vaginal deliveries. Further, women who

had sustained an OASI at a previous delivery had a ten times higher risk of sustaining an OASI in subsequent vaginal deliveries.(147) The present study found no association between previously reported risk factors for OASI or postpartum AI, such as prolonged active pushing in the second stage of delivery, macrosomia, episiotomy and epidural anaesthesia (**paper I** and **III**), except occiput posterior presentation among those incontinent at six months postpartum.

It has been suggested that obstetric trauma and OASI are related to subsequent development of postpartum FI (14, 19, 64, 74), and that major tears involving both sphincter muscles are associated with increased risk of loose stool incontinence in particular.(119) Furthermore, it has been shown that 4th degree OASI or OASI involving the IAS muscle reflect a more severe injury, increasing the risk of FI postpartum, compared to OASI involving the EAS muscle only.(14, 119) One study reported 4th degree OASI and persistent OASI defect as identified by endoanal ultrasound to increase the risk of AI 10 months postpartum.(74) Further, Fenner and co-workers (2003) found that women with a 4th degree OASI were ten times more likely to report problems with bowel function compared to women with a 3rd degree OASI.(54) It has been argued that the PRM muscle may compensate for the diminished sphincter muscle function in patients with disruption of the IAS or EAS, provided that the factors contributing to the complex mechanism of anal continence are not compromised.(136) Thus, the degree of OASI may not be related to the type and severity of AI symptoms reported. Furthermore, some authors argue that rather than being risk factors of postpartum AI, OASI and factors associated with OASI (episiotomy, macrosomia, prolonged second stage of labor, occiput posterior position and operative delivery) may be markers of a difficult delivery with the potentially confounding synergistic impact of more than one risk factor occurring during labour.(19, 23, 92, 131) Only one third of the women who sustained an OASI at delivery and responded at all three time points in **paper III**, reported AI 1yPP. This may suggest that the

delivery related factors influence postpartum AI to a lesser extent than pregnancy related factors. However, as only six women participating in the present study sustained an OASI including the IAS muscle at delivery, we were unable to explore the association between degree of OASI and AI.

5.1.3 Anal incontinence and impact on Quality of Life

5.1.3.1 Quality of Life and symptom severity

Nearly one in ten of the 1571 participating young, healthy, pregnant women experiencing AI symptoms reported a moderate to strong negative effect of AI symptoms on their QoL. Similar to previous reports, the mean scores in the four FIQL domains in late pregnancy were only slightly reduced from the maximum score.(32, 141) In the literature, there is conflicting evidence as to whether frequency and severity of AI symptoms appropriately indicate the impact on QoL (22, 43, 76), and it has been argued that due to the complexity of maintaining anal continence, individual differences in impact on QoL is to be expected.(43, 84) Some authors suggest that the impact on an AI sufferer's well-being and QoL is reflected by the St. Mark's score and dependent on symptom severity.(42) Others report persistent AI symptoms postpartum to negatively affect QoL, and that QoL was affected more by severe symptoms as compared to less severe symptoms.(76) The results in the present study are similar to previous reports (11, 42, 61, 66, 76), and indicate that various types and combinations of AI in late pregnancy affect QoL differently. Roos and co-workers (2010) reported women with 3c and 4th degree OASI to have more defecatory symptoms and poorer QoL compared to women with 3a or 3b OASI. However, they found no association between sustaining OASI of any degree and reductions in QoL, and suggest that impact of AI on QoL may be due to other factors such as pain or anxiety, rather than defecatory difficulties.(119) In a recent study by Soerensen and co-workers (2013) on the other hand, the overall impact of AI symptoms on QoL was low. However, increasing severity in AI symptoms was found to be significantly

associated with reductions in reported QoL 20 years after sustaining an OASI at delivery.(131) Overall, the women experiencing a combination of all AI symptoms in the present study reported a profound impact on all four FIQL domains. These findings are in concordance with reports from previous studies.(18, 43, 117)

5.1.3.2 Quality of Life and flatus incontinence

When compared to women experiencing urgency alone in the present study, women experiencing flatus incontinence alone weekly or more reported a profound impact on QoL and the strongest association was found in the domain “Embarrassment”. Previous studies have indicated that flatus incontinence at any frequency is the least bothersome AI symptom.(22) Others have found that 30 years after delivery, bothersome flatus incontinence was more common among women following OASI compared to women undergoing episiotomy or caesarean section.(106) Both the St. Mark’s score and the Wexner score have been criticised for including flatus in the assessment of AI, and it has been suggested that FI and flatus incontinence ought to be assessed separately.(126) In **paper I**, however, both formed and loose stool incontinence were found to be strongly associated with flatus incontinence in late pregnancy, as well as one year later. Further, FI and flatus incontinence were also found to have similar predictors both in late pregnancy and 1yPP. Experiencing flatus weekly or more often was defined as an AI symptom in all three papers included in the present thesis. This definition is based on previous reports of flatus being the most predominant AI symptom postpartum (3, 59), involving substantial psychological distress and embarrassment to some patients.(112) Further, Guise and co-workers (2007) argue that even though incontinence of flatus often is regarded as less severe than other AI symptoms, this frequently experienced symptom may cause considerable embarrassment in social settings for many young women. They thus suggest that flatus ought to be part of the routine questioning in postpartum visits.(59)

5.2 Potential bias

5.2.1 Response rate

The response rate in the present study was approximately 50%. This is in concurrence with most epidemiological studies concerning AI in relation to pregnancy and after delivery.(32, 52, 59, 73, 145) Previous reports indicate that questions regarding AI are less frequently answered than other questions.(77, 78) In a Dutch study, the main reasons given for non-participation were time investment and the intimate nature of the questions.(145) Studies including invasive testing with physical assessment of PFM function, including manometry, have reported further recruitment problems and patients declining participation.(50)

5.2.2 Non-responders

In the present study, we were unable to collect data on the non-participating primiparae from the two participating hospitals. However, the socio-demographic characteristics such as mean age, number of participants aged 35 years or older and educational level are similar to previous Norwegian studies on pregnant women.(73, 133) Further, data from the Norwegian Birth Registry on women giving birth in Norway show that the national mean age for primiparous women was 27.6 years in 2010, only slightly lower than the mean age of 28.2 years in the present study (Table 1, **Paper I**) However small, the difference in mean age between the responders and non-responders has made the interpretation of the results rather challenging as it has been difficult to determine whether age is a confounding factor or a risk factor or not. Age was thus subsequently included in the multivariate logistic regression models in all three papers.

When compared to women responding both in late pregnancy and one year later, the women who only responded to the first questionnaire regarding symptoms in late pregnancy tended to be younger, less educated and unemployed at start of pregnancy. Further, fewer non-responders were married, and more non-responders smoked during pregnancy. This response pattern is similar to previous studies and the response rates have been reported to be lower among single women, those aged less than 25 years and women with low education in several studies. (23, 32, 34, 59, 78)

Few primiparae of Asian ethnicity were included in the present study (data not shown). Other studies have reported a high level of non-participation in women representing minority groups, especially among women with a different first language than the national language where the study was undertaken.(32, 78) The questionnaire used in the present study was in Norwegian only and it may thus have led to a selection bias and exclusion of women from

minority groups with limited knowledge of the Norwegian language. The prevalence of AI found in the present study was similar to previous studies primarily including Caucasian women.(132) Some evidence suggests that Asian ethnicity is associated with an increased risk of persistent FI six years postpartum.(79) A recent study on the prevalence of AI among primiparae in China found that the prevalence of flatus incontinence was markedly higher one year after delivery than in the present study. However, the prevalence of FI symptoms among the Chinese women was lower both in late pregnancy and postpartum than in the present study.(37)

Some authors suggest that women returning for further assessment or responding to multiple questionnaires tend to have a higher motivation or prevalence of symptoms requiring follow-up than non-responders.(35) This selective non-response in longitudinal studies may influence the results and thus lead to a systematic bias, and it may also reduce the generalisation of the findings and threaten the validity of a study.(72) On the other hand, low socioeconomic status has previously been reported to be associated with poorer health status and increased risk of morbidity in numerous illnesses and conditions.(2, 27, 146) In the present study, however, the prevalence of AI among all the women responding to the first and third questionnaire (**paper I**) was similar to the AI prevalence among the 862 women responding at all three time points (**paper III**), both in late pregnancy and one year after delivery. Considering the factors increasing the risk of AI identified in paper I, and young age at delivery and unemployment in particular, the dropout rate may indicate an underestimation of AI in the present study. Furthermore, it is unlikely that the participants aged younger than 23 years have completed higher education prior to giving birth to their first child and additionally some may be unemployed or employed only part-time while attending higher education. These factors may thus have a synergistic effect, emphasizing the complexity of past partum AI, and further

complicate the process of identifying risk factors. The potential correlation between age, unemployment and education level was not found to invalidate the criteria for regression analyses, and these factors were entered into the multiple logistic regression models in **papers I and II**, though due to low numbers, unemployment was not included in the multiple logistic regression models in **paper III**.

5.2.3 Quality of the measuring tools

In the present study, the use of self-administrated questionnaires and patient reported outcomes may have led to information bias due to the possibility of incorrect reports, incomplete reports, or participants misunderstanding questions.(72) The percentage of missing data was low in the present study, and between 0.3% and 2.2% in the outcome measures of AI using the St. Mark's score, and 0.4% and 1.7% for the FIQL scores. The percentage of missing data was considered to be too small to have an important impact on the results and a simple imputation procedure was thus used to replace missing items in completed questionnaires.

The validity of a measuring tool concerns the extent to which it measures what it is intended to measure, while reliability concerns the precision of the measurements when using the tools. The FIQL scale was originally designed as a self-administrated questionnaire (116), and psychometric evaluations have shown that the scale is both reliable and valid.(38, 108, 116, 142) Findings from one study, however, indicate that the FIQL scores were somewhat lower when administered by telephone as compared to self-administration.(71) Further, some authors suggest that the somewhat poorer test-retest results found in the FIQL domain "Embarrassment" may be due to a possible placebo effect, as discussing the experience of AI symptoms with a health professional may reduce the feelings of shame and embarrassment at

the follow up visit.(108) The St. Mark's score on the other hand, was originally designed and validated as a questionnaire used in patient consultation and in an interview setting.(144) Some evidence suggests that the test-retest reliability of the St. Mark's score is inadequate, and that it may therefore be unsuitable for use as a self-administered questionnaire.(10, 126) However, Maeda and co-workers (2007) demonstrated a reasonable sensitivity when the St. Mark's score was used as a self-administered questionnaire. Further, the St. Mark's score showed good correlation with patients' subjective perception of symptom severity.(84) Previous studies have indicated that the FIQL in particular, may be too time-consuming and complicated for clinical use.(18) However, the use of self-administrated and anonymous postal questionnaires may in turn encouraged the participants to reveal a more detailed description of their experience of AI symptoms as compared to for instance face-to-face interviews or socially desirable answers in clinical settings and follow-up consultations.(10, 22)

In the present thesis, the prevalence of AI and associations between the different AI symptoms (**paper I and II**) and continence statuses (**paper III**) are presented, as well as associations between AI symptoms and background variables, rather than the total St. Mark's score as reported by most studies. Three of the items on the St. Mark's score were not included in the statistical analyses; "alteration of lifestyle", "pad use" and "constipating medication". This was based on findings from previous studies and the fact that the present study included QoL and data reported on the FIQL scale. Bols and co-workers (2010) suggest that these three items may reflect a patients' self-confidence more than the severity of AI, and thus not change as readily as the other items on the St. Mark's score.(20) Further, pad use equals a score of two points on the St. Mark's score. Maeda and co-workers (2009) have indicated that this question may not be truly reflective of a patient's severity of symptoms, as

fewer men than women used pads, and a woman's use of pads may be related to reasons other than AI or FI.(83) Women with no episodes of stool leakage may wear pads as they worry about potential accidental leakage.(140) The total St. Mark's score and the individual items, except "pad use" and "use of constipating medication", have been found to be adequately sensitive to change.(18, 20, 126)

Bakx and co-workers (2005) found that the St. Mark's score distinguished between patient groups, with large differences in AI complaints following colorectal surgery. However, the St. Mark's score did not distinguish between patient groups with smaller differences in AI.(10) Bols and co-workers (2010) found that changes in the total St. Mark's score reflected the patient's subjective improvement after treatment with PFME.(20) Both these studies included patients with long standing AI, higher mean age and total St. Mark's scores than in the population of the present thesis. The reported findings may thus not be comparable to our population of young healthy primiparae. In contrast, the majority of young, healthy women reported only minor AI symptoms on the St. Mark's score following primary repair of OASI in a study by Roos and co-workers (2009), and experiencing AI symptoms was found to be significantly associated with impact on QoL as measured by the Manchester Health Questionnaire.(120) In a study by Pauls and co-workers (2008) (110), the impact on QoL and FIQL scores were slightly lower, though similar to the findings in late pregnancy in the present thesis (**paper II**). Furthermore, the FIQL scores reported by Pauls and co-workers (2008) remained stable throughout the period from early pregnancy to six months postpartum.(110) Unfortunately, the results from the present thesis did not allow for evaluation of AI and impact on QoL one year after delivery, as few women reported FIQL scores below the chosen cut off points (data not shown).

5.3 Anal incontinence and treatment

Traditionally, treatment for AI has consisted of primary or secondary repair of OASI, sacral nerve stimulation, conservative treatment with PFME, stopping medication and dietary advice.(91, 103, 105) Previous reports indicate that the success rate of primary and secondary repair of the anal sphincter muscles is reduced in the long term (149), and that approximately 50% of women with OASI report AI postpartum.(119, 134, 147) The effect of pelvic floor muscle exercises (PFME) in prevention and treatment of urinary incontinence in general, during pregnancy and postpartum, is well documented in the literature.(17, 25, 95, 96, 104, 124, 133) However, there is scarce documentation of the effect of PFME on AI symptoms.(25, 26, 104, 133) PFME may in theory improve the mechanism maintaining anal continence and closure of the anal canal by improving the strength and function of the PRM, IAS and EAS muscles, in largely the same manner as indicated in the treatment of UI.(26, 47) Furthermore, it has been questioned whether it is possible to distinguish between a voluntary contraction of the EAS muscle as compared to a general voluntary PFM contraction.(104) However, there is evidence suggesting that PFME may reduce co-existing AI in patients referred with UI (57), and increase the ability to correctly contract the pelvic floor and sphincter muscles and subsequently reduce AI symptoms.(56, 86) Further, PFME as part of a general exercise program in mid to late pregnancy has demonstrated a protective effect among multiparous women only.(133)

The main findings in the present thesis indicate that AI among pregnant and first time mothers is a common problem. Furthermore, a substantial number of healthy young pregnant women report AI symptoms to affect their QoL. In view of the suggested association between prevalence of AI symptoms at nine months after delivery and long term prevalence of AI

documented previously (112), these findings may aid in the identification of pregnant and postpartum women who may require further intervention.

5.4 Cost of anal incontinence

It has been estimated that the financial burden of AI for patients as well as society is relatively large, and it may increase in the future due to an aging population and direct costs related to medical care and treatment, as well as indirect costs related to factors such as the loss of productivity.(41, 92, 148) Increasing costs of FI have been shown to be associated with symptom severity and female gender, whereas age was found not to be associated with reduced costs among patients experiencing AI for more than one year.(148) Among older patients with longstanding FI, loss of productivity in paid and unpaid work accounted for half the estimated total cost of FI.(41) Identifying women with AI symptoms affecting QoL in the first year postpartum may reduce the long term adverse effect of AI both with regards to personal as well as societal costs.

5.5 General discussion

Our findings support the argument in some studies that pregnancy related changes are the main cause of postpartum pelvic floor disorders (73, 81), whereas others argue that perineal trauma, OASI and neurological trauma are the main contributing factors.(19, 70, 107) The current national guidelines in Norway (139) and in the UK (122) recommend routine follow-up postpartum of women sustaining an OASI at delivery, regardless of continence status and individual need of medical attention and follow-up. Some authors suggest that OASI and operative deliveries are indicators of complications occurring during labour, synergistically mediating a postpartum development of AI symptoms.(19, 23, 92, 131) Furthermore, some studies have indicated that the misclassification of perineal tears is highly prevalent, and true

occult injuries are rare.(4) Moreover, the diagnoses of an OASI depend on the health professionals' knowledge, experience and skill and previous studies have reported inadequate training and knowledge of anatomy of the pelvic floor muscles among midwives and obstetricians.(4, 97) Even though OASI has been shown to be associated with an increase in the risk of reporting AI symptoms postpartum in several studies (19, 134, 147), other factors such as operative deliveries, malpositioning of the foetus during delivery, age, incontinence symptoms presenting pre-pregnancy or during pregnancy and persisting postpartum, educational level (7, 48, 73, 92, 132, 134) may also be directly or indirectly associated with postpartum AI symptoms.

In concurrence with a previous study (59), the findings in the present study may suggest that experiencing flatus incontinence less frequently than once per week is regarded as normal or close to normal, and not bothersome enough to have an impact on QoL, as opposed to flatus incontinence on a more frequent basis. Furthermore, embarrassment and coping behaviour are considered to be two of the most important aspects of patients' daily lives and several authors have reported that few AI sufferers volunteer information or seek medical help for their AI symptoms.(6, 22, 76) Results from previous studies also indicate that embarrassment and coping behaviour are the main reasons for not seeking medical care and non-disclosure of AI symptoms.(12, 43) The results from the present studies support the on-going initiative of increasing the awareness among health professionals about reducing the prevalence of OASI at delivery, as well as risk factors and treatment for AI and the impact on QoL.(134) Furthermore, the present findings indicate that frequent flatus incontinence is considered as more than a minor inconvenience among young, expectant mothers. Thus, it may be that the national recommendations ought to be extended to include women experiencing bothersome AI in pregnancy as well as postpartum, based on symptoms reported, rather than being offered exclusively to those sustaining an OASI at delivery. Offering early intervention and advice to

those with AI affecting their QoL in pregnancy and postpartum may reduce the long term effects of AI for both the AI sufferer personally as well as societal costs. Further, increasing the knowledge about available AI and treatment options and where to seek advice among those at risk of AI in pregnancy and postpartum may reduce the embarrassment and reluctance to seek medical advice.

The St. Mark's score and the FIQL scale were chosen as measuring tools in the present thesis based on previous findings and evaluations of validity, as discussed earlier. Further, both questionnaires are used in clinical practice and research worldwide, as well as in our own clinical setting. During the planning of the present thesis, the evaluations of other scoring systems were scarce, and it was thus decided that these scoring systems were adequate to use in this study. Considering the inconclusive documentation of the psychometric properties of the St. Mark's score and that recent evaluations have indicated that the FIQL scale may be too time-consuming and complicated for clinical use (5, 18, 20, 142), we have tried to take this into consideration when interpreting the results.

Considering the risk factors found in the present study, the protective effect of higher education in late pregnancy (**paper I**), as well as the socio-demographic and socioeconomic differences between participants responding to the first or both questionnaires, the prevalence of AI postpartum, may cause an underestimation rather than an overestimation of the associations between AI symptoms, risk factors and QoL. Further, some of our findings may be explained by the association between lower socio-economic status and inequalities in health documented earlier.(2, 27, 143, 146) However, the background, cause and impact of health inequalities is a complex topic and may be confounded by a number of behavioural and psychosocial factors such as age, physical activity, work satisfaction and locus or feeling of

control (146). These are factors not measured in this study which may have influenced the prevalence and predictors of AI found in the present study and the predictive effect of the socio-demographic factors found in this study must thus be interpreted with caution.

6. Conclusions

The thesis explores prevalence and predictors of AI among primiparous women as well as impact on Quality of Life. The results may be summarised as follows:

6.1. Conclusion paper I

One in three primiparae experienced AI in late pregnancy. One year later still one in four suffered from AI. Sphincter injury predicted incontinence of stool and flatus, while higher age and operative delivery predicted urgency.

6.2. Conclusion paper II

Between 3-10% of the primiparous women in the present study experienced AI to such a degree that it affected QoL. The strongest impact was seen in the QoL domains “Coping Behaviour” and “Embarrassment”.

6.3. Conclusion paper III

More women experienced persisting AI symptoms at twelve months postpartum, as compared to women with new onset AI. Young age and AI in late pregnancy or six months postpartum increased the risk of AI at twelve months. These results may indicate that hormonal and mechanical changes in pregnancy affect postpartum AI more than vaginal delivery.

6.4 General comment

It appears that the hormonal, mechanical and neuromuscular changes occurring during pregnancy are the most important predictors of postpartum AI, while any trauma during the delivery may add to these functional defects, and thus create some new onset incontinence.

Identification and adequate follow up of pregnant women with AI may reduce AI after delivery. Further, these findings highlight the importance of an increased awareness on AI in late pregnancy among health professionals, and the need to implement routine discussions about AI with expectant mothers.

7. Implications of findings & suggestions for future research

The present thesis has explored the short term prevalence of AI in primiparous women. The results indicate that AI is a common feature in pregnancy and postpartum among young healthy primiparous women. Some predictors are potentially modifiable, such as high BMI and operative deliveries. Further, the predictors identified in the present study may aid in improving the knowledge about who may be at risk of AI in pregnancy and postpartum as well as tailoring intervention according to the women's individual needs both in pregnancy and after delivery, regardless of perineal tear status at delivery. Certain AI symptoms or combination of symptoms have been found to have a profound impact on QoL, increasing the evidence base that AI symptoms often regarded as less bothersome, such as frequent flatus incontinence, in fact are the symptoms affecting QoL of these young healthy women the most.

The different aetiologies and individual importance of the specific symptoms of anal incontinence emphasize the complexity of postpartum AI, complicating the process of identifying risk factors. The results in the present thesis emphasise the need for improving the knowledge about AI and available treatment options among health professionals and women at risk of AI in pregnancy and the first year after delivery in order to minimise the potential long term adverse effects and cost of AI.

Further research is warranted in this field, and particularly with regards to the efficacy of conservative treatment and PFME, and which patients to target for effective conservative treatment. More specifically, some suggested areas for further research are as follows:

- Explore effect of conservative treatment with PFME for AI in pregnancy as well as postpartum both as primary and secondary preventative measure with structured treatment for those experiencing AI symptoms pre-pregnancy or during pregnancy.

- OASI and misclassification, how many are missed and do they result in AI symptoms postpartum.
- Qualitative research into how these women are met by health professionals and how to best offer advice and treatment
- Interventions to increase the awareness of risk factors for AI in pregnancy and postpartum among health professionals such as community midwives, physiotherapists and GPs outside the anorectal specialist clinics and women's health clinics.

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