Pelvic girdle pain and disability during and after pregnancy

A cohort study

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Doctoral Thesis

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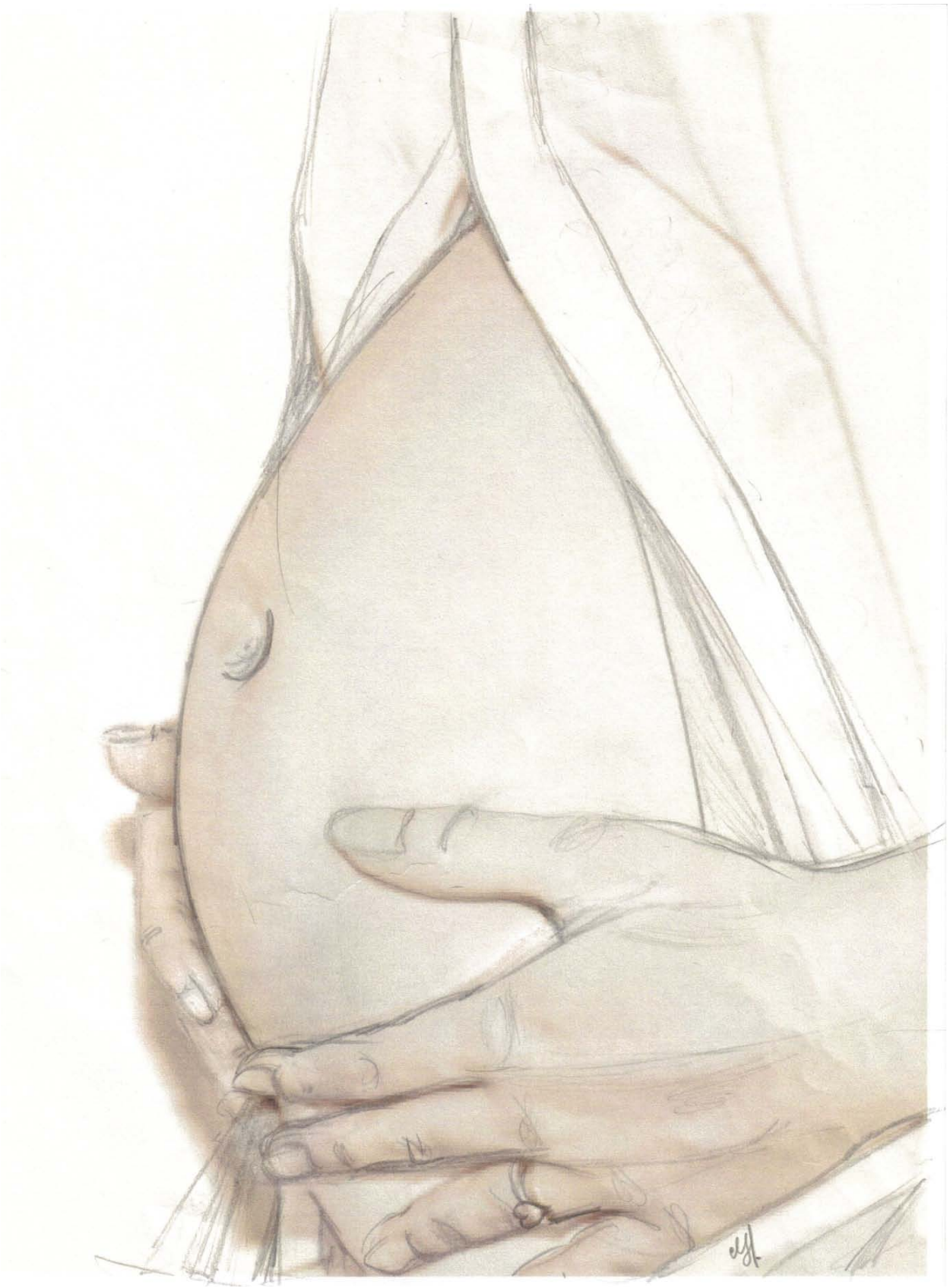

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2 SUMMARY

Background: Pelvic girdle pain (PGP) is a frequently reported musculoskeletal disorder that impacts the activity level in pregnant women. However, the prevalence and severity of this condition during and after pregnancy is unsure. To gain a better insight into underlying factors potentially influencing PGP, it is of interest to examine how pelvic girdle pain and disability are associated with responses to some frequently used clinical tests.

The reported prevalence of PGP in pregnancy varies considerably in previous studies. Even though most women with PGP in pregnancy seem to recover shortly after delivery, it has been reported that a considerable number of women develop chronic PGP, resulting in pain and functional problems postpartum. Therefore, aiming at limiting negative consequences of PGP during and after pregnancy, it is important to identify risk factors for development of PGP in pregnancy as well as for sustained PGP postpartum. Previous studies have reported that typical risk factors for development of PGP include history of low back pain before pregnancy and PGP in previous pregnancies. However, it would be of interest to also identify more clinically relevant factors that could possibly be targeted by treatment strategies.

A main focus in the clinical examination of women with PGP is to distinguish between pain located in the pelvic area or in the low back area. However, in addition, it is also important to explore the associations between the responses to frequently used pelvic tests and the severity of PGP during and after pregnancy.

Aims: The main objective of this thesis was to explore factors related to pelvic girdle pain and disability during and after pregnancy, and to estimate the prevalence of PGP at different times. The specific research objectives were: to examine the associations between the responses to clinical tests and disability in gestation week 30. Furthermore, to identify risk factors for development of PGP and disability during pregnancy as well as for sustained PGP and disability 12 weeks postpartum.

Material and methods: A total of 326 women recruited from four maternity care units in the Oslo area gave informed consent for participation in the study. Data were collected by questionnaires and clinical examinations at inclusion (mean gestation week 15), in gestation week 30, and 12 weeks postpartum. Prospective and cross-sectional designs (gestation week 30) were used and the response variables were disability (measured by the disability rating index, DRI) and pain intensity (measured by visual analogue scale, VAS). Variables identified in previous studies (socio-demographical and psychological factors) as well as self-reported pain locations defined from pain drawings and responses to clinical tests were used as explanatory variables (risk factors in paper II and III). The data were analyzed using different statistical approaches, including tests for comparisons of groups and bivariate and multivariable regression analyses for associations.

Results: Prevalence of self-reported PGP was 35%, 62% and 31% at inclusion, gestation week 30, and 12 weeks postpartum respectively. Large variation in disability (DRI) was

found at all times independently of the presence or absence of PGP. Pregnancy itself resulted in increased disability, and PGP gave an additive effect.

In the cross-sectional study of data from gestation week 30 multivariable analyses resulted in strong associations between pain locations within the pelvic area, responses to the posterior pelvic pain provocation (P4) test and the active straight leg raise (ASLR) test and disability.

Among the clinical factors assessed in early pregnancy, self-reported pain locations in the pelvic area, response to the P4 test, and sum of positive pain provocation tests were risk factors for disability and pain intensity in gestation week 30. In addition distress was associated to disability.

Among the clinical factors assessed in gestation week 30, the sum of positive pain provocation tests was a risk factor for both disability and pain 12 weeks postpartum. Furthermore, number of pain sites in other areas of the body was a risk factor for pain intensity 12 weeks postpartum and pre-pregnancy low back pain was a risk factor for disability. Pre-pregnancy body mass index was associated with both disability and pain intensity and response to the ASLR test was associated with disability, though none of them significantly.

Conclusions: The high prevalence of PGP during and after pregnancy indicates that there is a need for attention by health care providers. The large variation in disability seen among the women at all times regardless of the presence or absence of PGP shows that pregnancy itself impacts function. Furthermore, the results support the common clinical experience that there is a large variation in affliction among women with PGP. The different risk factors identified for development of PGP in pregnancy and for sustained PGP 12 weeks postpartum emphasize a need to distinguish between these phases. The identification of clinical risk factors for PGP is a novel finding and probably of importance in further development of treatment and prevention strategies

3 LIST OF PAPERS

I Hilde Stendal Robinson, Anne Marit Mengshoel, Elisabeth K Bjelland, Nina K Vøllestad.
Pelvic girdle pain, clinical tests and disability in late pregnancy
Manual Therapy, 15 (2010) 280-285

II Hilde Stendal Robinson, Marit B Veierød, Anne Marit Mengshoel, Nina K Vøllestad. **Pelvic girdle pain – associations between risk factors in early pregnancy and disability or pain intensity in late pregnancy: a prospective cohort study**
BMC Musculoskeletal disorders, 2010

III Hilde Stendal Robinson, Anne Marit Mengshoel, Marit B Veierød, Nina K Vøllestad. **Pelvic girdle pain; potential risk factors in pregnancy in relation to disability and pain intensity three months postpartum**
Manual Therapy, 2010

4 ABBREVIATIONS

ASLR; The Active Straight Leg Raise test

CI; Confidence Interval

DRI; Disability Rating Index

FABQ; Fear Avoidance Beliefs Questionnaire

HSCL; Hopkins Symptom Check List

HRQL; Health Related Quality of Life

IQR; Inter-quartile Range

LBP; Low Back Pain

LDL; Longs dorsal sacroiliac ligament

MCU; Maternity Care Unit

mFABQ; Modified Fear Avoidance Beliefs Questionnaire

ODI; Oswestry Disability Index

OR; Odds Ratio

P4; The Posterior Pelvic Pain Provocation test

PGP; Pelvic Girdle Pain

SIJ; Sacroiliac Joint

SD; Standard Deviation

SPSS; Statistical Package for Social Science

VAS; Visual Analogue Scale

5 DEFINITIONS and TERMINOLOGY

5.1 Pelvic Girdle Pain (PGP)

In this thesis PGP is understood as musculoskeletal pain located within the pelvic area (i.e. below the lumbosacral junction and above the gluteal folds) that develops in relation to pregnancy. The participants were asked if they had pain in the pelvic area, and eventually where the pain was located. No Norwegian terms synonymous with PGP were used either in the questionnaires or in the examinations. Nevertheless our understanding of PGP is in accordance with the definition from the European guideline group of 2008:

> "Pelvic girdle pain (PGP) generally arises in relation to pregnancy, trauma, arthritis and osteoarthritis. Pain is experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints. The pain may radiate in the posterior thigh and can also occur in conjunction with/or separately in the pubic symphysis.'' [106]

5.2 Low Back Pain (LBP)

In this thesis LBP is understood as pain in the lower back, located above the lumbo-sacral junction with or without radiation in the leg(s). Hence our understanding of LBP is narrower than definitions being used by others,[100;109] but in accordance with a previous study of PGP.[69]

5.3 Lumbopelvic pain

When no specific distinction is made between LBP and PGP, the condition is referred to as lumbopelvic pain in keeping with several studies,[87;114] i.e. this definition includes both PGP and LBP. To our understanding, this definition is in accordance with the definition of low back pain used in the European guidelines from 2006:

> "Low back pain is defined as pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without leg pain." [100]

5.4 Disability

In this thesis the term disability is used in the meaning of reduced physical function (e.g. difficulties doing activities like outdoor walks, climbing stairs, running, carrying a bag, etc.)

6 BACKGROUND

Before I started my academic career, I had about 20 years of experience as a physiotherapist and manual therapist in clinical practice, treating patients mainly with musculoskeletal disorders. During these years, I have met many women suffering from pain in the pelvic area during pregnancy and after delivery. The complexities in their stories as well as in their clinical pictures gave me a number of questions to bring along into this field of research.

The main goal for treatment using physiotherapy and manual therapy is to relieve pain and to restore or maintain the patients' physical function.[111] When treating the women with pregnancy related pain in the pelvic area, I experienced that my treatment often fell short, without understanding why and also that several women did not recover as expected after delivery. Their ability to take part in daily activities and to earn a living could be reduced. My question was: Why did some women develop chronic problems, while others recovered?

My clinical experience indicated that musculoskeletal pain in the pelvic area seemed to have a very different influence on the women's lives and that the condition was complex to understand and difficult to treat. I ended up being curious about the course of pain in the pelvic area during and after pregnancy, and I wanted to know more about risk factors for developing such pain as well as for non-recovery after delivery. Most of all I lacked and wanted more knowledge about risk factors that we really could manage - or treat - in clinical practice, risk factors that could be helpful in decision making to determine who needs treatment and who does not. I also questioned the increase in prevalence for pelvic girdle pain (PGP) in pregnancy, which has been reported during the last 20 years. Furthermore, I wondered whether any of my clinical tests actually could help me identify the tissue causing the pain and tell me something about prognosis.

Before I started my work as a PhD student, I cooperated with researchers at the Norwegian Institute of Public Health, analyzing data from a population study including questions about PGP.[80] The main result was that prevalence of PGP in pregnancy was 46% in this cross-sectional study. Work on this paper inspired me to enroll as a doctoral student, and to plan the cohort study together with my supervisors.

Hence, this thesis is based on my persistent curiosity about pregnant women and pain in the pelvic area. I believe that by improving our understanding of risk factors for development of PGP we can provide a basis for new approaches to both the prevention and treatment of the condition. I assumed that in a prospective design not influenced by recall

bias, the prevalence of PGP in pregnancy would be lower than 46%.[80] When introducing clinical examinations we would also acquire more information about pain locations, the tissue involved, and also the degree of affliction. It seemed important to find out if the clinical examination could provide information about the development of PGP during pregnancy and the risk for sustained problems after delivery. I thought that if we studied PGP in a cohort of pregnant women, it would also be possible to evaluate the effect of pregnancy itself on function and disability throughout pregnancy and in the postpartum period.

7 INTRODUCTION

Pregnancy is supposed to be a happy period of life for women, associated with great expectations for the immediate future: the pregnancy period, the delivery, the child and motherhood. Among many women it seems to be an expectation that life continues more or less normally during pregnancy. Nevertheless, previous studies have shown that a large number of pregnant women report PGP.[35;37;48;80] This condition impacts negatively on many of the daily activities, especially weight bearing activities such as walking and standing and several women have problems moving around.[33;37;48;80] Hence, PGP affects both the activities of daily life and the quality of life during pregnancy.[67] It has been an accepted understanding that PGP is most frequently experienced late in pregnancy, and that it disappears after delivery. However, studies have shown that several women do not recover as expected during the postpartum period, but instead develop chronic pain and report significantly lower health related quality of life than healthy women.[88;89] It has also been reported that PGP is the major cause for sick-leave among pregnant Scandinavian women,[32;92;93] and the costs to society may be great.

A better understanding of the development of PGP as well as an identification of risk factors would be important for treatment and prevention purposes.

7.1 Prevalence of PGP

Several studies have examined the prevalence of PGP during and after pregnancy, and large variations in the estimates have been reported (ranging from 4 % to 90 % in pregnancy).[114] Furthermore, the condition has been looked upon almost as a "normal consequence of pregnancy that the woman must endure".[33] Recently published guidelines reveal that several studies suffer from methodological limitations such as lack of definitions of pain and diagnostic criteria for PGP. [106] Moreover, comparison of the results between studies may be problematic since the study designs and selection of the study population often differ. In some studies, women with PGP may also have been overrepresented due to the procedures. The European guideline group suggested that the prevalence of PGP in pregnancy is about 20%,[106] based on four studies,[5;8;48;71] and that the evidence from this estimation is strong. However, this prevalence estimation can be questioned; since recently published studies have reported that the prevalence of PGP late in pregnancy may be more than 50%.[35;61;67]

It has been an understanding and also a persistent assumption that pregnant women in Scandinavia report PGP more frequently than women in other countries. Even though the majority of studies of PGP have been carried out in this area, there are studies from several other countries as well,[9;59;63;81;99] indicating that PGP could be a more universal problem than a purely Scandinavian one.[7]

Most of the women with PGP in pregnancy recover shortly after delivery, but studies over a longer follow-up period have reported that between 5 % - 7 % of the women suffer from sustained PGP for two years and longer after delivery.[2;65] Again it is difficult to compare results across studies, since they differ in several methodological aspects.

7.2 Affliction

PGP has an impact on the pregnant women's function and is exacerbated due to weight bearing activities (like walking and standing).[74;106] In clinical examinations of musculoskeletal disorders in general, the assessment of function is an important factor for providing effective management of patients.[111] Hence, it seems important also to study how, and to what degree, PGP afflicts pregnant women. Apart from a few recently published studies,[35;67;80] previous studies have been more concerned with the prevalence of PGP than the consequences of having PGP. In clinical practice a large amount of information is collected in order to be able to provide patients with optimal treatment, to set relevant goals and also to evaluate the effect of treatment.[111] It is now common to view health and health related quality of life no longer as dependent only on the individual, but rather as complex results of biological, psychological and social factors in accordance with the International Classification of Functioning, Disability and Health (ICF).[112]

When evaluating affliction from PGP it seems incomplete to only obtain data about presence and absence of PGP, the intensity of pain as well as disability is also important. Hence, graded scales are necessary.

7.3 Potential causes of PGP

The causes of PGP in pregnancy are not well understood, and both mechanical and hormonal factors are suggested.[3;27;46;54;72] The pelvis can be regarded as a main bony platform, connected to the spine and legs, which have to be stabilized during weight bearing activities

and movement. Relaxation of the pelvic joints is seen as a normal physiological response to pregnancy. The relation between relaxation and pain is not established, although one empirical suggestion is that relaxation of the ligaments leads to instability of the pelvic joints (sacroiliac joints (SIJ) and pubic symphysis), which then again leads to pain. Hence the increased mobility in the SIJ has been understood as a cause of PGP.

There have been discussions and disagreement over the years concerning the degree of mobility in the SIJ and the association between mobility and pain. The mobility of the SIJ is slight and according to the work by Sturesson and co-workers, no differences in mobility were found between symptomatic and asymptomatic SIJ when using roentgen stereo photogrammetric analysis.[90] Furthermore, they concluded that the increased mobility could not be the cause of the pain. Later on, Damen and co-workers used Doppler imaging of vibrations in their studies, and examined the mobility in the SIJ.[19] Their results showed that asymmetric mobility in the SIJ was associated with PGP. Nevertheless the relationship between mobility in the pelvic joints and PGP is still unclear.

7.4 Pain distribution

The associations between pain locations and the structures possibly responsible for the pain are not well documented or understood. Based on the understanding that relaxation of the SIJ might be the cause of PGP, efforts have been made to explore the pain referral patterns (pain distributions) from the SIJ.[25;26] Different types of injections into the joints and adjacent areas in combination with clinical tests and procedures have been used to examine the correlation between pain location and clinical tests.[49;51;52] The criticisms against the published pain referral patterns from the SIJ are founded on the contention that they identify pain coming from within the joints, rather than considering that pain might also come from extra-articular structures close to the joints. The latter might explain why the pain distribution described in the definition of PGP from the European Guideline group is broader than the referral map of SIJ pain presented in previous studies.[25;26;106] Based on the results from several studies combining injections and clinical tests, Laslett and co-workers suggested that the symptoms and signs of PGP and the SIJ are concurrent and that the results from clinical tests are identical for the two conditions.[49] Furthermore, that PGP and SIJ pain could represent the same entity when pain in the pubic symphysis is excluded from PGP.

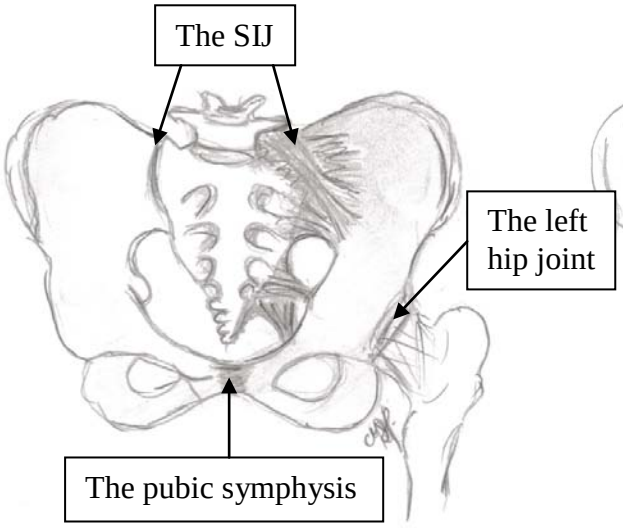


Figure 1 Front view of the pelvis. The right SIJ is shown without ligaments.

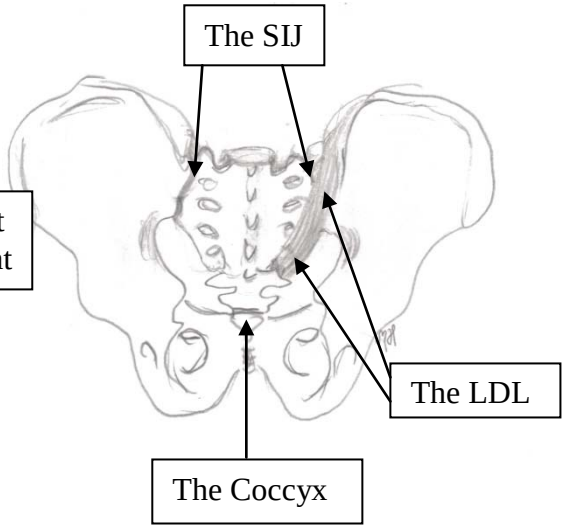


Figure 2 Back view of the pelvis. The long dorsal sacroiliac ligament (LDL) is shown on the right side.

7.5 Clinical examinations and tests

The use of different criteria makes it difficult to compare diagnoses and classifications of PGP in both research and clinical work.[5;48] Usually the clinical diagnosis is made on the basis of two sets of information: i) self reports of pain and functioning and ii) clinical findings. Information for example on pain location, pain-provoking actions, history of low back and pelvic girdle pain, limitations in daily activities and demographic variables are usually collected in clinical practice as well as by interviews or questionnaires in epidemiological studies. It has been an understanding that pain located to the area of the SIJ and/or pubic symphysis is characteristic symptoms for PGP.[106] Difficulties in walking have been reported as a typical symptom in several studies,[43;91] and have also been mentioned as diagnostic criteria.[48]

The clinical examination of patients with musculoskeletal pain in general, focuses on identifying the underlying mechanisms of the pain (pathophysiology) and the functional status. This information is used as a guide to provide adequate treatment.[16] Clinical tests are most often used to confirm a symptom (pain) or presence of a sign (for example instability). The underlying empirical premises are that the tests reveal information about involved structures and mechanisms and that specific signs and symptoms need specific therapeutic

actions. Although pain may be referred, it is commonly assumed that identification of the structures or mechanisms involved may be a helpful method by which to identify more homogeneous subgroups. Clinical examinations include functional tests and pain provocation tests. The clinical examinations of women with PGP aim at obtaining further information on pain location, pain-inducing situations, (in)stability and mobility of joints, side differences in mobility or muscle activation and the ability of the neuromuscular system to stabilize the pelvic joints. A number of different tests are applied both in research and in clinical practice when examining women with PGP. The posterior pelvic pain provocation (P4) test and the functional Active Straight Leg Raise (ASLR) test are of particular interest due to their theoretical and empirical relevance for PGP.[57;58;74]

Previous studies have emphasized the importance of discriminating between pain from the lower back and pain from the pelvic area,[35;42;44;75;91] and it has been suggested that the diagnosis of PGP can only be reached after exclusion of lumbar cause of pain, and functional disturbances must be reproduced by specific clinical tests.[106] Several tests intend to meet these requirements. For example, the (passive) straight leg raise test, related to suspected nerve root pain and possible involvement of the intervertebral discus, are one test used for differential diagnostic purposes.[100] The McKenzie system also has elements in their examination procedures that are assumed to identify possible discogenic pain.[21] However, these procedures are often used in combination with pain provocation tests for the pelvic joints,[35;51;115] tests that have shown variable degree of reliability.[50;79;97] The extent to which a golden standard for validity exists may also be questioned.[98] Furthermore, few of the actual tests have been examined for their ability to discriminate between PGP and LBP, but rather between no pain and PGP.

In general, a clinical evaluation of low back pain should be sufficient to identify red flag conditions and to decide whether nerve root pain is present.[100] Even though previous studies have reported that the presence of sciatica in pregnancy is uncommon,[47;71] this could be important to keep in mind also when examining pregnant women.

The evidence that supports the association between the different classifications of pain location and clinical tests as well as their association to disability in pregnant women is still lacking. Consequently, there is a need to study these associations further.

7.6 Risk factors for development of PGP

Several possible risk factors for development of PGP in pregnancy have been examined, and a recent review reported a total of 15 possible risk factors for lumbopelvic pain (combination of LBP and PGP) in pregnancy.[114] Strong evidence was reported for strenuous work, previous LBP, and previous PGP as risk factors. However, several of the included studies were cross-sectional and used only bivariate statistical methods. Hence they are not methodologically sufficient to provide information on risk factors for development of PGP, but only on associations and correlations (table 1).

The European guideline group concluded that the risk factors for development of PGP most probably are a history of LBP prior to pregnancy and previous trauma to the pelvis.[106] Furthermore, the group stated that contraceptive pills, time interval since last pregnancy, height, weight, smoking and most probably age were not risk factors. Again, these conclusions must be interpreted with caution because inappropriate statistics were used in some of the original studies (table 1).

Over the past 15 years, firm evidence has been established for the importance of fear-avoidance beliefs and psychological distress as contributors to low back pain.[15;102;110] Due to the similarities between LBP and PGP one may hypothesize that these factors are also important for the development of PGP. Furthermore, since PGP reportedly influences weight bearing activities, fear of increased pain due to activity may be an important risk factor. For LBP the effect of fear avoidance beliefs is seen even at very early stages of the clinical course,[14;31] suggesting that it may be important to investigate whether these factors are present in early pregnancy and represents risk for development of PGP. It has been suggested that low back disability is causally related more to fear avoidance than to pain or physical pathology,[109] but similarly, this has not been examined for PGP. Grotle and co-workers compared the level of fear- avoidance beliefs and distress in acute and chronic LBP.[31] The level of fear-avoidance beliefs and distress were lower in patients with acute LBP for the first time compared with patients with chronic LBP. Furthermore, fear-avoidance beliefs and distress were associated with disability in both acute and chronic LBP. According to the European Guideline group, the role of "yellow flags" has not been investigated among PGP patients, but, "based on the present limited knowledge, the impression is that yellow flags are less common among patients with PGP than with LBP".[106] One recently published study reported that in early pregnancy women with lumbopelvic pain reported higher levels of exaggerated negative thoughts and fear-avoidance beliefs than women without pain.[66] To our knowledge, fear

avoidance and distress have not been examined as risk factor for either the development of PGP in pregnancy or for sustained PGP postpartum.

Information from the patient's history and the clinical examination form the basis for diagnosis and management strategies in clinical work with patients, but there has been little focus on responses to clinical tests as potential risk factors for development of PGP. Nevertheless, risk factors could be more useful in the clinical work if they were helpful in development of priority strategies for prevention and treatment. Hence, most of the suggested risk factors from previous studies would be of little help.

Table 1: Studies examining risk factors for developing PGP in pregnancy

Author	**Design and statistical approach**	**Outcomes**	**Follow up – methods**	**Results**
Mantle et al. (1977) [55] n=180	Cross-sectional Associations	Backache	Questionnaire in labor ward	Age and parity were correlated with backache. No associations between back ache and height, weight, weight gain, baby's weight
Fast et al. (1987)[24] N=200	Cross-sectional Retrospective	LBP	Interview 24-36 hours postpartum	None of the variables (age, weight gain during pregnancy baby's weight, parity) were associated with LBP
Berg et al (1988) [8] n=862	Prospective Population based cohort Chi-square Associations	LBP (SIJ-dysfunction)	Questionnaire x 3 during pregnancy. Severe pain: examined* by orthopedic surgeon (n=72)	Previous history of LBP, heavy work and smoking were associated with LBP. Parity, exercise habits and work satisfaction not associated with LBP
Østgaard et al (1991) [71] n=855	Prospective Population based cohort Correlations	Back pain complaints (High, low and sacroiliac)	Questionnaire 7-9 times through pregnancy, Women with LBP: pain drawing and questionnaire	Previous history of LBP, parity, young age, heavy workload, poor work satisfaction were correlated with increased prevalence of back pain No correlation between back pain and use of contraceptive pills or weight increase during pregnancy
Orvieto et al (1994) [68] n=449	Cross-sectional Correlations, Chi-square, t-tests, ANCOVA	Low back pain	Questionnaire; Women recruited for an antenatal ultrasound examination	Low socioeconomic class, pre-pregnancy LBP, LBP during and between previous pregnancies were associated with risk for LBP Several ultrasonographic and obstetrical data, age, parity, gestational age, average maternal height, weight and BMI were not associated with increased risk for LBP
Kristiansson et al (1996)[45] n=200	Prospective Correlations	Back pain	3 times during pregnancy and 12 weeks after. Clinical examination *	More women with LBP had previous history of LBP, higher parity, larger weight increase during pregnancy No difference between no pain and LBP in smoking habits, age, BMI at first visit, time since last pregnancy

Larsen et al (1999) [48] n=1600 (followed afflicted women, n=227)	Prospective Logistic regression	Symptom giving pelvic girdle relaxation	Questionnaires, repeatedly: 227 of 1600 fulfilled criteria of pelvic pain and were examined* by rheumatologist	Risk factors: Previous history of LBP, pelvic pain in previous pregnancy, previous low abdominal pain, lack of exercise, bad working conditions No risk: Age, weight, carrying heavy loads at work, parity, smoking
Mogren and Pohjanen (2005) [62] n=891	Cross-sectional Logistic regression	Low back and pelvic pain (LBPP)	Questionnaire after delivery	Increasing parity, history of hypermobility, BMI and amenorrhea were associated with LBBP Age at menarche, use of oral contraceptive were not associated with LBPP
Albert et al (2006) [4] n=2269	Cross-sectional Retrospective Logistic regression	PGP (subgroups based on pain locations)	Questionnaire and clinical examination* in gestation week 33	Previous history of LBP, previous trauma of back/pelvis, parity, higher level of stress, low job satisfaction were associated with development of PGP Age, marital status, full-time work, contraceptive pills, previous stillbirth, interval between pregnancies, hormonal induced pregnancy, urinary tract infection, less desire to become pregnant, BMI>30 were not associated with PGP

* The women were examined, but results of clinical examinations were not used as potential risk factor for PGP/LBP in the analyses

7.7 Risk factors for sustained PGP postpartum

The European Guideline group concluded that the prevalence of PGP is about 20% in pregnancy and rapidly declines to about 7% three months postpartum.[106] This leaves a rather high number of women suffering from PGP after delivery, and thus underscores the importance of identifying risk factors for non-recovery. One of the main reasons for identifying risk factors for development of chronic pain conditions is to be able to develop prevention strategies. PGP represents large costs for society; hence, a reduction in the number of women with chronic pain would be beneficial both for the women themselves and for the society as a whole. Studies of risk factors for sustained PGP postpartum have identified some of the same risk factors as for development of PGP during pregnancy.[106;114] History of back pain before pregnancy or during a previous pregnancy, high pain scores in pregnancy, reduced mobility in the hip joints and low social status are all identified as risk factors for sustained PGP after delivery (table 2). However, these studies are impaired by the use of different terminology and different definitions of pain locations, making it difficult to compare the results. Furthermore, methodological weaknesses and inappropriate statistics in several of the studies, render their conclusions on risk factors for sustained PGP postpartum insufficient.

It seems that little effort has been made to try to identify clinical risk factors for sustained PGP postpartum, and only a few studies have been found. Albert and co-workers divided PGP in pregnancy into sub-groups according to pain locations within the pelvic area.[2] Having pain in all three pelvic joints late in pregnancy was associated with a markedly worse prognosis after delivery than for other pain locations. Furthermore, a large number of positive clinical tests in late pregnancy gave high relative risk for persistent pain at two-year follow-up. Gutke and co-workers have identified combined LBP and PGP in pregnancy as a risk factor for sustained pain postpartum.[36] Vøllestad and Stuge identified high scores on the ASLR test and low score on beliefs in improvement three months postpartum as risk factors for non-recovery one year after delivery.[108]

It is of importance to examine if there are clinical factors present in pregnancy that are associated with sustained PGP postpartum. This information could be used to develop strategies that can prevent further development of chronic conditions. This is important for the women themselves as well as for health personnel concerned about women's health after pregnancy. Hence, it is a need for further studies that also include responses to clinical tests

as potential risk factors for sustained PGP postpartum. These should be prospective-design studies including appropriate statistics.

Table 2: Studies examining risk factors for sustained PGP postpartum

Author	**Design & statistical approach**	**Outcomes**	**Follow up – methods**	**Results**
Breen et al (1994) [10] n=1042	Prospective Pregnancy data collected retrospectively Multiple regression	Postpartum back pain	Interview after delivery and questionnaire 2 months later	Risk factors: history of back pain, weight, younger age, greater weight No risk: Height, mode of delivery, neonatal birth weight and epidural anesthesia
Ostgaard et al (1992) [70] n=817	Prospective Associations, comparison of means	Postpartum back pain	Questionnaire 12 months after delivery	Presence of back pain before pregnancy or during pregnancy, physically heavy work and multi-pregnancy were factors that correlated to postpartum back pain
Ostgaard et al (1996) [73] n=164	Prospective Correlations	Back pain and posterior pelvic pain	Questionnaire and examination. Treatment	High pain intensity during pregnancy correlated with little regression of pain after delivery
Brynhildsen et al (1998) [13] n=146	Cross-sectional Chi square, Mann Whitney, logistic regression	LBP and SIJ pain	Questionnaire 12 years after delivery Women with LBP/SIJ pain in pregnancy	Previous (severe) LBP during pregnancy and heavy occupation increased the risk for current non-pregnant LBP
Turgut et al (1998) [96] n=88 pregnant women, with back pain	Prospective T-tests, comparison of means	Back pain postpartum	Questionnaire in pregnancy and 1, 3 and 6 months after delivery	Women with a previous history of back pain had a higher prevalence of back pain 6 month postpartum, especially young multi-pregnant women
Albert et al (2001) [2] n=341	Prospective Correlations Bivariate analyses	Pelvic girdle pain (PGP)	From gestation week 33 re-examined in intervals for 2 years after delivery. Followed women with PGP pregnancy	Fewer women with combined symphysis and bilateral posterior pain recovered. High number of positive tests, reduced hip mobility, older age, non-education, unskilled work, high pain intensity were associated with pain two years postpartum

To and Wong (2003)[95] n=326 women, singleton pregnancies	Prospective, observational cohort Associations Chi-square, t-tests, Mann-Whitney	Back pain (BP)	Questionnaire in early postpartum (surveyed LBP in pregnancy retrospectively) and 24 months after delivery	Previous episodes of BP before or during pregnancy were associated with BP in pregnancy. Severe pain in early gestation and inability to reach pre-pregnancy weight were associated with BP 2 years postpartum
Mogren (2006) [61] n=639 women	Follow-up women with LBPP T-tests and Chi-square, logistic regression	LBPP (low back and pelvic pain)	Questionnaire just after delivery, and 6 months postpartum	BMI, hyper mobility, level and onset of pain during pregnancy were risk factors for persistent LBPP postpartum. Parity, gestational age, birth weight were not associated with persistent LBPP
Rost et al (2006) [82] n=430 pelvic pain patients	Follow up study Logistic regression	Pelvic pain	Questionnaire to women who delivered less that 42 months prior to follow-up (mean 18 months)	Pre-pregnancy back pain, severity of complaints, number of walking deficiencies as primary referral, duration of labor showed significant relation with symptoms in bivariate analyses. Only duration of labor in multivariable analysis
Vollestad & Stuge* (2008) [108] n=95, women with PGP	Prospective Multivariable regression analyses	PGP Pain and disability	Examined when included into the study (postpartum) and one year after treatment	ASLR test* and low score on beliefs in improvement were risk factors for non-recovery
Gutke et al (2008) [36] n=308	Prospective cohort study Multiple logistic regression methods	No pain, LBP, PGP, combined LBP/PGP	Examined in gestation week 12-18, sub grouped according to pain location and clinical examination**	Women with combined LBP/PGP had lower degree of recovery. Low endurance of back flexors, older age, LBP/PGP in early pregnancy, work dissatisfaction were risk factors for persistent PGP or LBP/PGP postpartum

*The only study identifying response to a clinical test as risk factor

** Response of clinical tests were not examined as possible risk factors for sustained PGP, LBP PGP/LBP, however pain locations were used.

8 AIMS

The main objective of the research presented in this thesis was to explore factors related to pelvic girdle pain and disability during and after pregnancy and to estimate the prevalence of PGP at different time points. The specific research objectives of the three papers were:

1. To examine the associations between pain locations, responses to the posterior pelvic pain provocation (P4) test and the functional active straight leg raise (ASLR) test as well as their associations with disability in gestation week 30 (paper I).
2. To identify socio-demographical, psychological and clinical risk factors in early pregnancy for disability and pain in gestation week 30 (paper II)
3. To identify risk factors in late pregnancy among women with PGP, for sustained disability and pain 12 weeks postpartum (paper III)

9 MATERIALS AND METHODS

9.1 Designs

The present thesis reports data from a large longitudinal study following a cohort of women from their first visit at the maternity care units (MCU), through their pregnancy period and up until one year postpartum. Data were collected at inclusion (mean gestation week 15), in gestation week 30 and 36, 6 and 12 weeks postpartum and one year postpartum. The present thesis includes three papers**.** In paper I a cross-sectional design was used analyzing data from gestation week 30. In paper II we used a prospective longitudinal design with one follow-up in pregnancy, analyzing data from inclusion and gestation week 30. In paper III we used a prospective longitudinal design with one follow-up postpartum, analyzing data from gestation week 30 and 12 weeks postpartum.

Figure 3 and 4 show flow charts of the entire study and the participants studied in the present thesis.

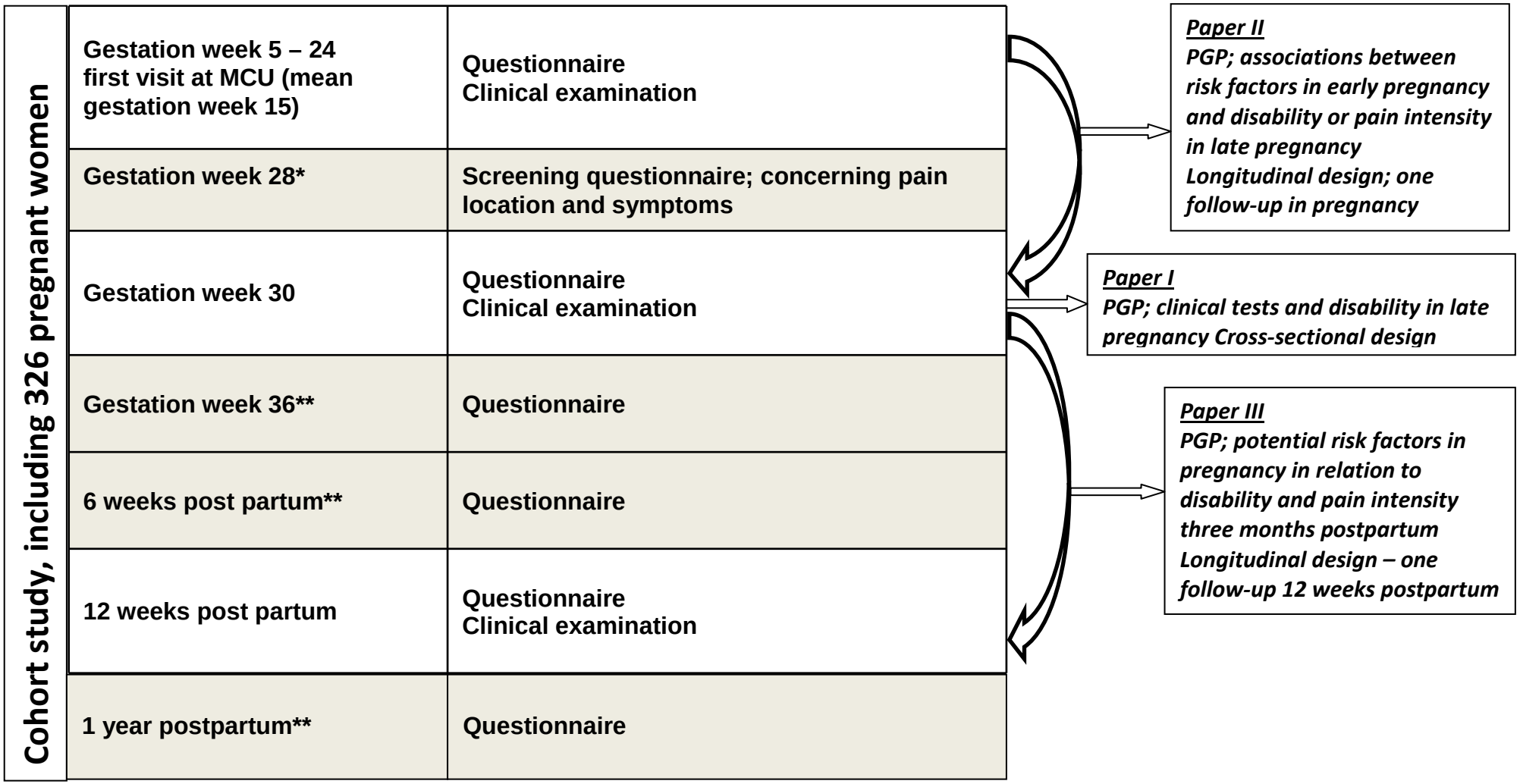


Figure 3: Flow chart over the time points for data collection of the entire study, and for the data included in the present thesis and the three papers.

* Data from gestation week 28 was used for selection of women for examination in gestation week 30.

**Data from gestation week 36, 6 weeks, and 1 year postpartum were not used in the papers in the present thesis.

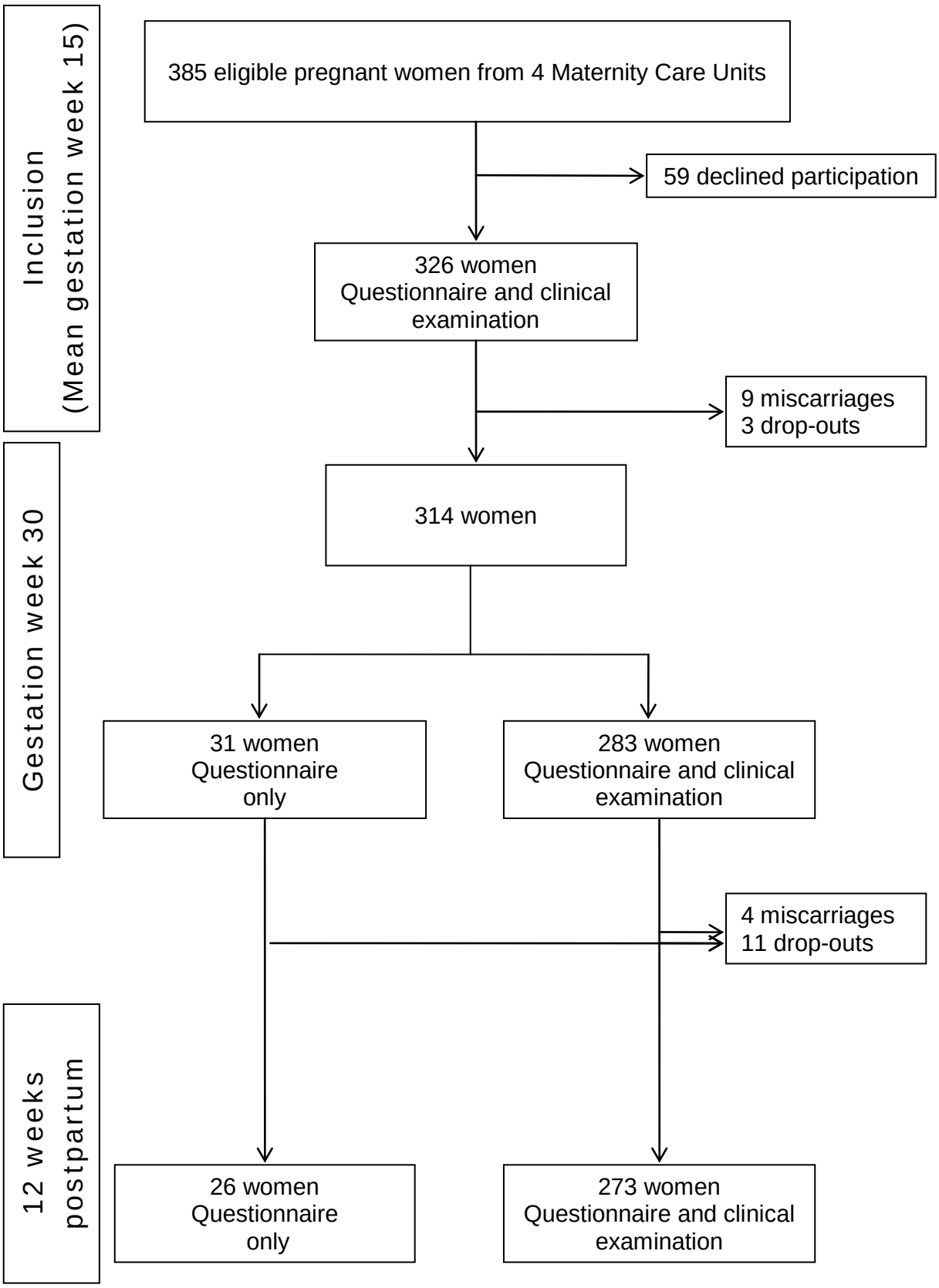


Figure 4: Flow chart showing the participants in the cohort study from inclusion to 12 weeks postpartum

Prior to the data collection, we composed the questionnaires for the study and included standardized questionnaires on health, health status, health locus of control, distress, fear-avoidance beliefs, and disability used in previous studies. In addition we included questions about socio-demographics, about pain and the locations of the pain. The contents of the questionnaires were discussed with experts on PGP, and tested out by letting 4 pregnant women fill them in, as a control for validity and feasibility. The questionnaires used at inclusion, in gestation week 30, and 12 weeks postpartum contained almost the same elements, expect for the socio-demographical variables (table 3).

The clinical examinations included six pain provocation tests for the pelvic joints as well as the functional active straight leg raise (ASLR) test. It also included Beighton score for hypermobility (only at inclusion), as well as general functional, mobility and stability tests. The clinical examinations in gestation week 30 and 12 weeks postpartum were identical, except for the examination of hypermobility (table 4).

Table 3: Contents of the questionnaires

	Inclusion	Gestation week 30	12 weeks postpartum
Socio-demographical data	X		
Modified FABQ	X	X	X
SF-36*	X	X	X
NHP*	X	X	X
Health Locus of control scale*	X		
HSCL-25	X	X	X
DRI	X	X	X
Physical activity	X	X	X
Questions about PGP and LBP	X	X	X
Complaints	X	X	X

* Data not used in the papers of this thesis.

FABQ, fear avoidance beliefs; SF-36, Short form - 36; NHP, Nottingham Health Profile; HSCL-25, Hopkins symptom check list; DRI, disability rating index; PGP, pelvic girdle pain; LBP, low back pain.

Table 4: Overview of the clinical tests included in the examinations

	Inclusion	Gestation week 30	12 weeks postpartum
Beighton score for hypermobility	X		
Fingertip-to-floor distance*	X	X	X
Schober's test*	X	X	X
Modified Trendelenburg's test#*	X	X	X
ASLR test#	X	X	X
P4 test#	X	X	X
Patrick Faber test#	X	X	X
Compression test#	X	X	X
Distraction test	X	X	X
Palpation of LDL#	X	X	X
Palpation of pubic symphysis	X	X	X
Joint play of SIJ#*	X	X	X

Used as sum of pain provocation tests (0-8) in the analyses

* data not used in the papers in this thesis
# performed on both sides

ASLR, active straight leg raise; P4, posterior pelvic pain provocation; LDL, long dorsal sacroiliac ligament; SIJ, sacroiliac joints

9.2 Participants and study samples

The Norwegian public health service offers all women free health service during pregnancy and most women visit special maternity care units (MCUs) for this purpose. We collaborated with four MCUs in the Oslo area; one was located in central Oslo (the capital city, about 580 000 inhabitants) whereas the other three covered one entire community just outside Oslo (about 24 000 inhabitants).

All Norwegian-speaking women signing in at these four MCUs between January 2006 and June 2007 were consecutively invited to participate by the personnel at the MCU. Women not expected to have a normal pregnancy (as determined by the midwives) as well as women presenting at high gestational age were excluded. Out of 385 eligible women, 326 gave their informed consent for participation after getting oral and written information about the study.

At inclusion all women answered a comprehensive questionnaire and were clinically examined by one out of two physiotherapists with post-graduate education in manual therapy. The examinations were performed at the respective MCU or at Hans and Olaf Physiotherapy clinic, located in the center of Oslo. To reduce bias, the examiner was not given access to any questionnaire data.[76]

The next examination of the women was carried out in gestation week 30. We examined women with symptoms from the low back or pelvic area, as well as women without PGP. The selection of women was based on a short questionnaire, including three questions about low back and pelvic pain, distributed by the midwives and answered by the women in gestation week 28. To be selected for a new examination in gestation week 30, the women had to report pain located in the pelvic area or low back area once a week or more, and the pain had to be provoked by sitting, standing or walking. Healthy women without these symptoms were also selected. This resulted in the exclusion of 31 women (9 %) who were not examined in gestation week 30, but questionnaire data were obtained and they continued in the cohort. Several of these women had minor symptoms from the area in question, but did not meet the entire set of criteria. This group ended up smaller than expected, because more women than expected had symptoms of PGP. In retrospect we found that examining all women at all times would have been possible. The handling of the selection was done by an external person, and the therapists carrying out the examinations were not given access to this information. Following this procedure, we called 290 of the 326 women for a new clinical examination in gestation week 30. Of these, 283 met and constituted the study sample in paper I.

Out of the 326 women in the cohort, 280 had been included before they reached gestation week 20 and were thus defined as being in early pregnancy. Nine of them had a miscarriage and three were drop-outs before gestation week 30. Since paper II aimed at identifying risk factors for development of disability and pain, the 268 remaining women constituted the study sample in paper II.

In paper III we aimed at identifying risk factors for non-recovery 12 weeks postpartum among women with PGP in late pregnancy. Hence, we needed criteria for constituting this group, and we decided to use self-reported pain combined with a level of disability. The 283 women who met for a new clinical examination in gestation week 30 were defined as afflicted if: 1) they reported to have PGP (yes, no) and/or had marked in the pelvic area on the pain drawing, and 2) they had a DRI score above the 25 percentile for the 283 women being examined in gestation week 30 (DRI>22). Both criteria were required, and resulted in 179 women afflicted with PGP and these women constituted the study sample in paper III.

Table 5 shows the characteristics of the total number of women in the cohort, the samples used for the different papers, as well as for the women that declined participation. There were only marginal differences between the groups.

Table 5: Characteristics of participants in the cohort and the different study samples used in the papers, and of those that declined participation

		Whole cohort n=326		Paper I n=283		Paper II n=268		Paper III n=179		Non-participants, n=59	
		Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)
Gestation age (weeks)		15 (5)		15 (5)		14 (3)		15 (4)		16 (5)	
Age (years)		31.5 (4.2)		31.3 (4.2)		31.3 (4.1)		31.3 (4.4)		30.7 (4.7)	
Weight (kg)		67 (11)		67 (11)		67 (11)		67 (11)		-	
BMI (kg/cm^2)		23.4 (3.5)		23.4 (3.5)		23.3 (3.5)		23.6 (3.7)		-	
Education (years)		16 (2)		16 (3)		16 (3)		16 (3)		-	
Employed			303 (93)		240 (85)		228 (85)		164 (92)		54 (92)
On sick leave at inclusion			62 (19)		54 (19)		49 (18)		43 (24)		-
Smoker			15 (5)		12 (4)		11 (4)		9 (5)		-
Parity	**0**		196 (60)		167 (59)		157 (59)		98 (55)		26 (44)
	1		103 (32)		92 (33)		86 (32)		64 (36)		30 (51)
	≥2		27 (8)		24 (8)		25 (9)		17 (9)		3 (5)

BMI, body mass index

9.3 Measurements of affliction

In paper I we used disability as a response variable, assessed by the Disability Rating Index (DRI) in gestation week 30. In paper II we used two graded scales as response variables, DRI and pain intensity (worst evening pain) assessed in gestation week 30. In paper III we used the same two graded scales; DRI and pain intensity (worst evening pain), measured 12 weeks postpartum, as response variables. In addition we also used a dichotomous response variable in paper III based on a combination of pain in the pelvic area and DRI. Salèn and co-workers reported that in a population of healthy persons with minor ailments the median value of DRI was 8.7 points (IQR 15.4).[83] Based on this, a cut-off of ten was chosen as a reasonable distinction between recovered and non-recovered women 12 weeks postpartum. The women in the present cohort were defined as non-recovered if 1) self-reported PGP and/or markings in the pelvic area on the pain drawing were present and 2) DRI was above 10.[83] This variable was assumed to distinguish those with affliction to a certain level from the others. The use of response variables are shown in table 6 and described below.

Table 6: Overview of the response variables used in the different papers

	Paper I	**Paper II**	**Paper III**
DRI, gestation week 30	X	X	
Pain intensity (VAS), gestation week 30		X	
DRI, 12 weeks postpartum			X
Pain intensity (VAS), 12 weeks postpartum			X
Recovered (yes/no)*			X

*Non-recovered was defined as pain in the pelvic area combined with DRI>10 points

DRI, disability rating index; VAS, visual analogue scale.

9.3.1 Disability (DRI)

To our knowledge, none of the existing questionnaires for measuring disability have been made especially for PGP. Previous studies of PGP have used different disability questionnaires, most often designed for use on patients with LBP. The Oswestry Disability Index (ODI) is widely used in back pain populations,[23] and it has also been used in studies of women with PGP.[35;88;89;108] However, all the questions included in the ODI are associated

with pain, and we considered it difficult for the women to give meaningful information if pain was not present. The latter would be the case for several of the women in the cohort.

In order to allow assessment of disability in women with and without PGP, we chose to use the DRI in the present cohort study.[83] DRI measures disability by assessing limitations in daily activities independent of pain. As for ODI, it was also primarily designed for patients with back pain. Although DRI has been less frequently used than the ODI, it has been used in studies of pregnant women before.[45;67;88] We evaluated the items as suitable for pregnant women with PGP or LBP as well as for pregnant women without pain. DRI consists of 12 items scoring the ability to perform activities of daily living (dressing without help, outdoor walks, climbing stairs, sitting for a longer time, standing bent over a sink, carrying a bag, making a bed, running, doing light work, doing heavy work, lifting heavy objects, participating in exercise/sport). The items were scored on visual analogue scales (VAS) ranging from 0 – 100 mm, with end points "ability to perform activity without restriction" and "inability to perform the activity". We calculated DRI as the mean of the twelve scales. Some of the criticism against using DRI in pregnancy is founded on the objection that it includes activities that pregnant women tend to stop doing (running for example); hence, a high score on DRI could be the result of pregnancy and not necessarily of PGP.[45;66;67] By including women independent of the presence or absence of PGP, our intention was to measure the possible effect of pregnancy on function as well as the additional effect of PGP. Furthermore, our clinical experience told us that women of today are increasingly likely to continue with their usual physical activities during pregnancy, and we expected that DRI could also be suitable to mirror this.

9.3.2 Pain intensity

It has recently been pointed out that pain is a symptom that is either present or absent, but when it is present, there may be a considerable variation in severity.[18] Furthermore, pain is a usual experience of adult human life.[39;40] Based on the assumption that there is a large variation in severity of pain, and since graded scales have been recommended,[18] we decided to use a measure of pain intensity. Since PGP increases with activity,[48;74] we evaluated the intensity of evening pain to be the most relevant measure for the degree of pain. It was measured by the response to the following question: "How intense is your worst PGP before going to bed?" The response was measured by a 0-100 mm visual analogue scale (VAS) and the end points were "no pain" and "unbearable pain".

9.4 Explanatory variables - potential risk factors

The selection of explanatory variables were based on the results from previous studies as well as on the hypothesis that the response to clinical tests could be risk factors for
1) development of PGP in pregnancy
2) sustained PGP postpartum
We measured the explanatory variables in early pregnancy (paper II) and in gestation week 30 (papers I and III)

9.4.1 Socio-demographical data

The following socio-demographical data were included in the questionnaire used at inclusion:

age (years)
marital status (single, married/cohabitant)
parity (0, 1, ≥2 children)
gestation week at inclusion
height (cm)
weight (kg)
education (≤12 years of school attendance, ≤4 or >4 years at university)
use of contraceptive pills last year before pregnancy (yes, no)
smoking status (yes, no)
physical activity before pregnancy (none, < 2, 2 - 4, > 4 hours per week)

Pre-pregnancy body mass index (BMI, weight/height^2) was calculated from self-reported height and weight, and was categorized as normal weight and overweight (<25 kg/m^2, ≥25 kg/m^2).[113]

We identified the women's working situation from the question: "How would you describe your work situation?" With four response alternatives: 1) Most of the time seated; 2) I have to walk a lot; 3) I walk and lift objects; 4) Heavy work. We categorized working condition as mostly seated work (response alternative 1) and heavy work (response alternatives 2-4). Furthermore, we also identified full-time work (yes, no).

9.4.2 Psychological data

The Hopkins Symptom Check List (HSCL-25) was used to measure distress (self-reported symptoms of anxiety, depression and somatization).[78] Twenty-five symptoms were recorded on a scale from 1 (not bothered) to 4 (extremely bothered). We calculated the average value to obtain the HSCL-25 score and used a cut-off value of 1.75 as established for women by Sandanger and co-workers (1998).[84] The cut-off value reflected non-specific distress, rather than a psychiatric diagnosis.

Fear avoidance beliefs were measured by the modified Fear Avoidance Beliefs Questionnaire (mFABQ).[53] This includes four of the items from the part concerning activity in the original Fear avoidance beliefs questionnaire.[53;110] We chose the modified version because it could also be answered by women without pain. In line with the work by Linton and co-workers,[53] we included the following introductory text in the questionnaire: "Some women will be afflicted by pain in the back and pelvic area during pregnancy. For research purposes, we would like to know if you believe that there is a relationship between such afflictions and activities. Please circle the number on the scale that best corresponds to your belief for each of the following statements." The scale ranged from 0 (total disagreement) to 6 (total agreement) and the total score on mFABQ ranged from 0-24.

9.4.3 Pain history and pain locations

Pre-pregnancy history of LBP was identified from the question: "Have you suffered from LBP before pregnancy (yes, no)?"

We calculated the number of pain sites from the questions asking the women if they had pain (yes, no) in the neck, shoulder and arms, between the shoulder blades, in the knees. The sum score (0-4) was used as a categorical variable in the analyses.

Pain located in the pelvic area and the low back area, were used as separate variables, determined from a pain drawing filled in by the women before each clinical examination. After the examination, the women were asked to point out the pain sites on their body and, if necessary, the examiner corrected the pain drawing to reflect the areas pointed out.

The pain locations in the pelvic area were subsequently coded: no PGP, pain in symphysis only, only posterior pain (uni- or bilateral), combined symphysis pain and unilateral posterior pain, and combined symphysis pain and bilateral posterior pain (figure 5 and 6). We coded pain above the level of L5/S1 to be LBP (figure 7).
To avoid bias, the examiner was blinded to the pain drawings until after the examination was performed.

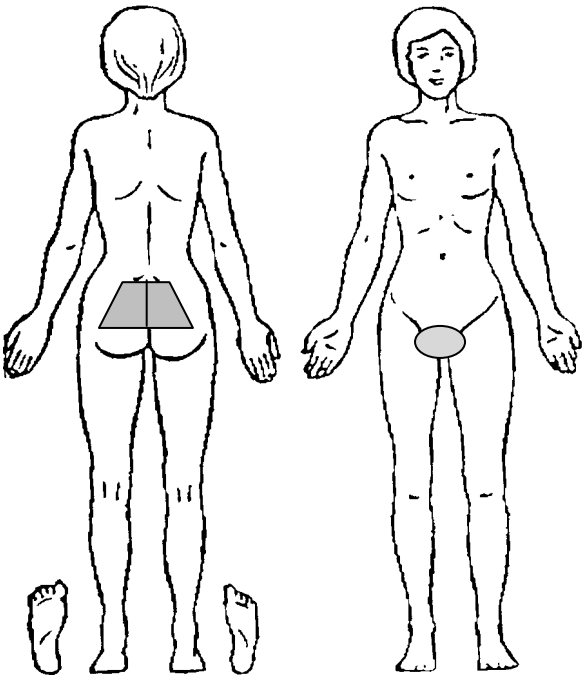


Figure 5: Illustrations of areas required for classification as combined symphysis pain and bilateral posterior pelvic pain*

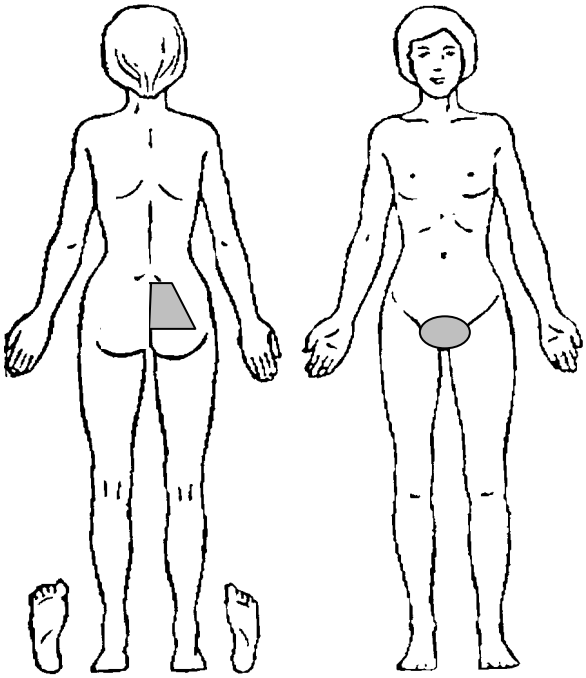


Figure 6: Illustrations of areas required for classification as combined symphysis pain and unilateral posterior pelvic pain*

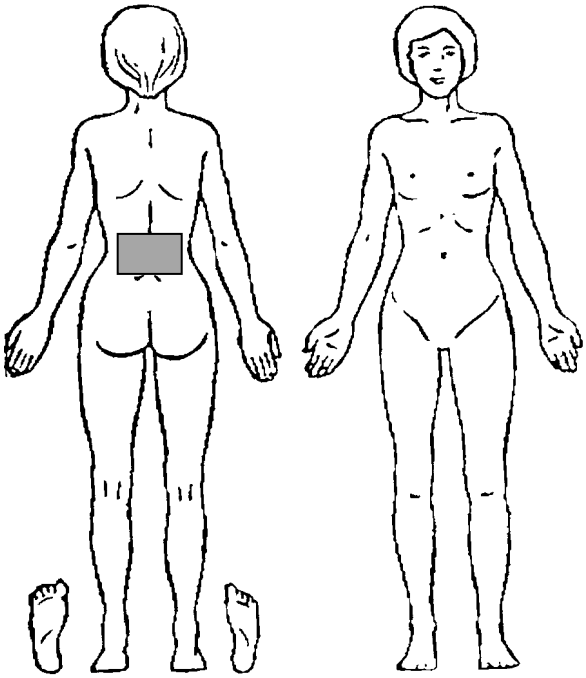


Figure 7: Illustrations of areas required for classification as LBP*, irrespective of radiating pain to the leg(s)

*The pain drawings are used with the kind permission from Professor Elisabeth Ljunggren, Physiotherapy Research group, Department of Public Health and Primary Care, University of Bergen, Norway

9.4.5 Clinical examination

The clinical examinations included the functional active straight leg raise (ASLR) test, the posterior pelvic pain provocation (P4) test and the following pain provocation tests: the distraction test, the compression test, the Patrick Faber test, the palpation test of the pubic symphysis and the palpation test of the long dorsal sacroiliac ligament (LDL). When assessing the pain provocation tests, we recorded if a familiar pain was provoked. All tests are commonly used, and moderate to excellent inter-rater reliability has been reported.[50;56;74;79;97;98]

The ASLR test (figure 8):[56] was performed with the women in a supine position with straight legs and feet about 20 cm apart. The women lifted each leg separately about 20 cm above the bench and was asked to score the difficulty on a six-point scale from 0 (not difficult to lift) to 5 (impossible to lift). The scores on both sides were added and the ASLR test ranged from 0-10. We used the ASLR as a categorical variable (sum score: 0, >0 in paper I and III, sum score <4, ≥4 in paper II).

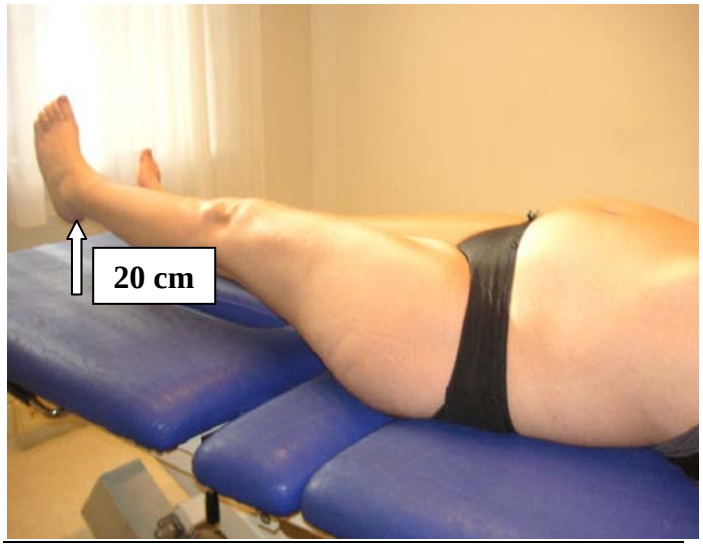


Figure 8: The ASLR test

The P4 test (figure 9):[74] was performed with the women in a supine position. The hip on the tested side was flexed to 90°. The examiner stabilized the contralateral side of the pelvis and applied a graded force on the flexed knee into the pelvis along the longitudinal axis of femur. Adduction of the hip was avoided. It was recorded whether a familiar pain was felt in the posterior part of the pelvis on the provoked side (yes, no).

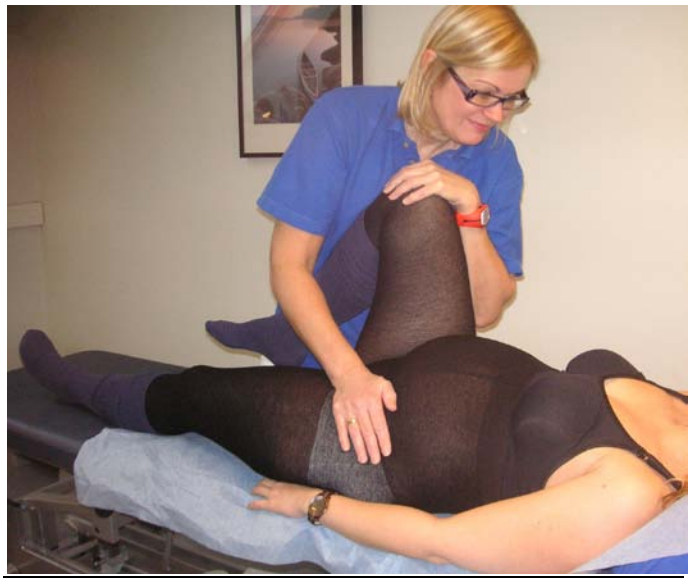


Figure 9: The P4 test

The scores were added and used as a categorical variable (sum score: 0, 1, 2). According to Østgaard and co-workers, the anatomical origin of the provoked pain is unknown and several anatomical structures may be involved and responsible for the pain reaction.[74]

The distraction test (figure 10):[52] the women were examined in supine position. The examiner applied cross-armed pressure to the anterior superior iliac spines directed laterally. This procedure was assumed to stretch the anterior sacroiliac joint ligaments and give compression in the dorsal part of the sacroiliac joints. It was recorded whether pain was felt in the posterior or anterior part of the pelvis. The pain response was recorded (yes, no).

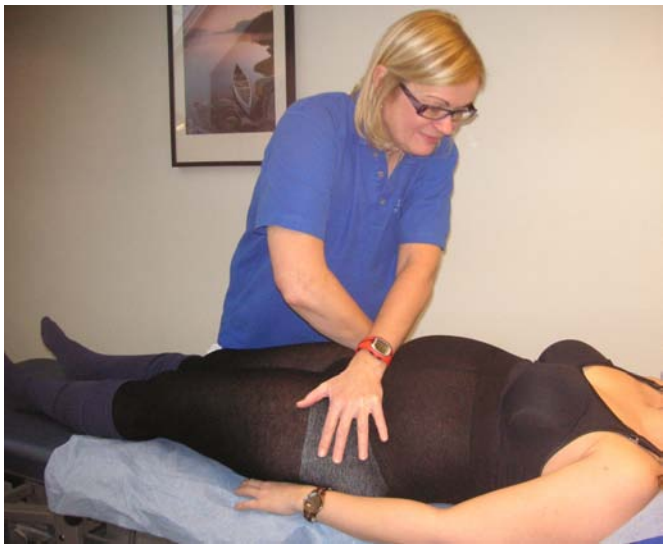


Figure 10: The distraction test

The compression test (figure 11):[79] the women were examined in side-lying position, knees and hips slightly flexed. Pressure was applied vertically into the pelvis when the examiner leaned her chest against the uppermost iliac crest. The test is assumed to stretch the posterior sacroiliac joint ligaments and compress the anterior part of the sacroiliac joints. Both sides were tested and scored separately. The pain response was recorded (yes, no).

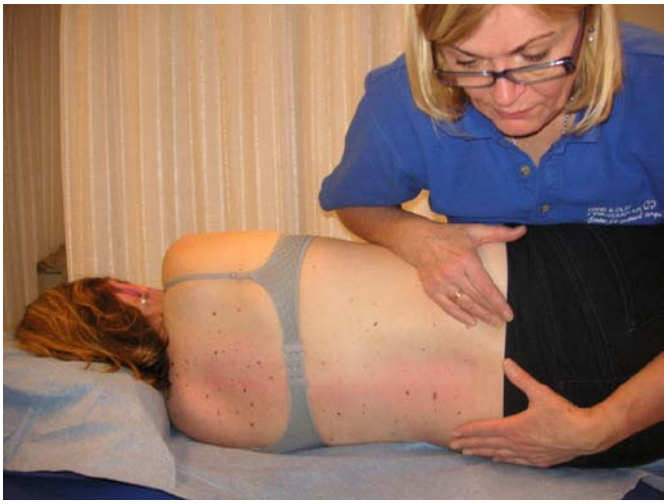


Figure 11: The compression test

The Patrick-Faber test (figure 12):[12;86] the women were examined in supine position. The examiner led the ipsilateral leg into flexion, abduction and external rotation so that the heel rested on the opposite kneecap. The examiner stabilized the contralateral side of the pelvis to ensure that the lower back stayed in a neutral position. The ipsilateral knee was lowered against the bench and the examiner applied a light overpressure to the subject's knee. It was assumed that both the anterior sacroiliac ligament and the hip joint were stressed. Both sides were tested and scored separately. The pain response was recorded (yes, no).

Figure 12: The Patrick-Faber test

Palpation of the pubic symphysis (figure 13):[1] the women were examined in supine position. The examiner applied gentle pressure to the pubic symphysis with her hand (flat fingers). If the pressure caused pain that persisted more than five seconds after removal of the hand, it was recorded as pain (yes, no).

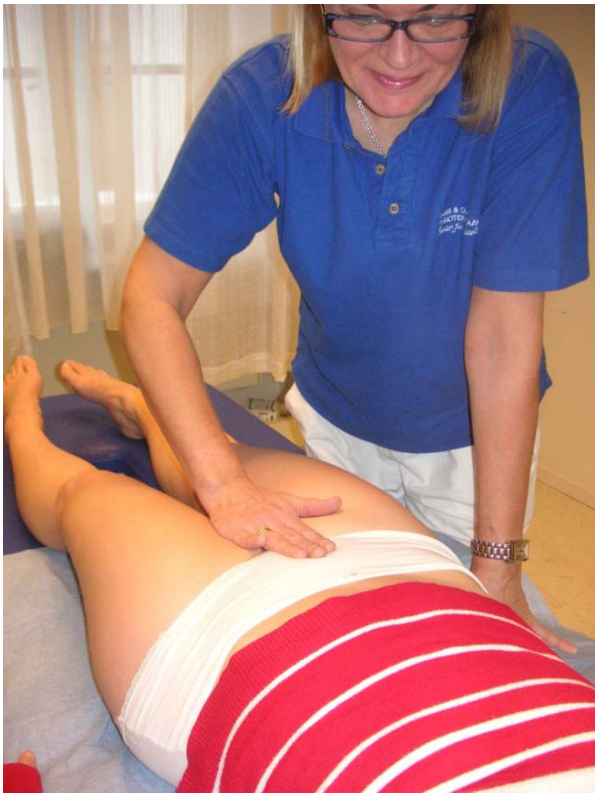


Figure 13: Palpation of the pubic symphysis

Palpation of the long dorsal sacroiliac ligament, LDL (figure 14):[107] the women were examined in side-lying position and the examiner palpated the LDL at the uppermost side, caudal of the posterior-superior iliac spine. The test was positive if the palpation provoked a familiar pain and was recorded (yes, no). Both sides were examined and scored separately.

Figure 14: Palpation of the LDL

In paper I we used the responses to the ASLR test and the P4 test from the examination at inclusion. In paper II we used responses to all the clinical tests presented above, performed at inclusion. In paper III we used the responses to all the tests presented above, performed in gestation week 30. For paper II and III we added all positive responses to the above described pain provocation tests, apart from the P4 test, ranging from 0 (all negative) to 8 (all positive). We used this sum score as a continuous variable in the analyses for paper II, and as a categorical variable with four levels in the analyses (0-1, 2-3, 4-5 and 6-8 positive tests) for paper III. Based on the P4 test's specific relevance for PGP reported in previous studies,[34;74] we decided to use the P4 as a single response and not as part of the sum score of positive pain provocation tests. ASLR test was also used as a single response (table 7).

The Beighton score[99] was used as a measure for joint hypermobility. It consists of 9 tests: hyperextension of the knees (yes, no), hyperextension (>10°) of the elbows (yes, no), passive apposition of the thumbs to the flexor aspect of the forearm with straight elbow (yes, no), passive hyperextension of the 5th metacarpophalangeal joints $\geq 90^{\circ}$ (yes, no), forward flexion of the trunk, with knees straight, so that the palms of the hands rest easily on the floor (yes, no). We measured all angles with a goniometer. A sum score (0-9) was made of the results of all the tests and hypermobility was defined when the sum score was four or higher.[99;101]

Table 7: Overview of explanatory variables used in the different papers

		Paper I	Paper II	Paper III
Socio-demographics	Age	X	X	X
	Marital status	X	X	X
	Parity	X	X	X
	Height	X	X	X
	Weight	X	X	X
	Pre-pregnancy BMI	X	X	X
	Education	X	X	X
	Smoking status	X	X	X
	Pre- pregnancy physical activity		X	X
	Working condition		X	X
	Full time work		X	
	Gestation week at inclusion		X	
	Use of contraceptive pills year before pregnancy		X	X
Psychological variables	mFABQ		X	X
	HSCL-25		X	X
Pain history and pain locations	History of pre pregnancy LBP		X	X
	Pain locations (pain drawings)	X	X	X
	Number of pain sites (0-4)		X	X
Clinical examination	P4 test	X	X	X
	ASLR test	X	X	X
	Sum of pain provocation tests (0-8)		X	X
	Beighton score for hypermobility (≥4)		X	

Sum of pain provocation tests included the distraction and compression tests, Patrick Faber test, palpation of the pubic symphysis and LDL (sum 0-8). Pain locations were pain in the low back area and/or the pelvic area (symphysis pain only, posterior pain only, combined symphysis pain and unilateral posterior pain, combined symphysis and bilateral posterior pain). Number of pain sites included pain in: the neck, shoulder and arms, between the shoulder blades, and the knees (sum score 0-4). BMI, body mass index; mFABQ, modified fear avoidance beliefs questionnaire; HSCL-25, Hopkins symptom check list; P4, posterior pelvic pain provocation; ASLR, active straight leg raise.

9.5 Ethics

The Regional Committee for Medical Research Ethics and the Norwegian Social Science Data Services gave formal approval of the study. All participants received written and oral information about the study. The women signed an informed consent before they were included in the study.

This cohort study was an observational study, and we did not offer any treatment for the women with PGP. If the women asked for advice concerning pain, activities, and treatment we answered their questions. Concerning further questions on treatment, we followed the usual procedures at the MCUs and left it to the midwives to refer women to physical therapy clinics in the local neighborhood.

9.6 Sample size and power estimates

We estimated power in several ways due to the different analyses used in the three papers in this thesis. The estimate of sample size for the study was primarily based on the expected prevalence of PGP. We calculated the sample size (n) from the following equation:

$$n=1.96^2p(1-p)/a^2$$

where "p" was the estimated prevalence (given as a fraction) and "a" was the chosen significance level. After reviewing the literature, we found that using a prevalence of PGP of about 20 % in late pregnancy was reasonable. This was also in accordance with the later published estimation of prevalence from the European Guideline group.[104-106] Hence, we used p=0.20 and a=0.05 when calculating power. This resulted in n=246. However we needed to include more than 246 pregnant women in the cohort because the use of different subsets of the study sample might be necessary in the different analyses. Hence, we included a total of 326 pregnant women in the cohort.

Continuous variables were the main responses in the studies in this thesis and were also used in the power calculations for the correlation and regression analyses. The level of significance was set at 5 % (two-sided) and the power at 80 %. Assuming a correlation of medium size, 0.3, in the population, a sample size of 85 is required for assessing significance of a correlation coefficient in the sample.[17] In a multiple regression analysis with five independent variables, the required sample size is 91 to detect a medium effect size of 0.15 ($R^2/(1-R^2)$).[17] If we increased the number of independent variables to 8, the

required sample size is 107,[17] thus the power should be sufficient since the study samples was 283, 268 and 179 women in papers I, II and III respectively.

For the logistic regression analyses, the "rule of 10" says that the sample size is large enough if the size of the least frequent outcome group is greater than 10 times the number of variables in the model. [38]

9.7 Statistical analyses

Several types of statistical analyses were used depending on the research questions and the variables used. Details regarding analyses are presented below. We used a 5 % level of significance in all papers. Statistical analyses were conducted using the statistical software program SPSS (version 15 for paper I and version 16 for papers II and III).

9.7.1 Paper I

Chi-square statistics were used to explore the strength of associations between the results of the clinical tests and the different pain locations. A one-way between-groups analysis of variance was conducted to explore the association between the pain locations and DRI. Due to the large number of comparisons involved, the Bonferroni post hoc adjustment was used to reduce the risk for Type 1 errors.[6] Multiple linear regressions were used to explore the relationship between DRI (response variable) and the P4 test, the ASLR test and pain locations (explanatory variables). Interaction effects between the variables were tested, and the residuals were examined to check model assumptions.

9.7.2 Paper II

Multiple linear regression analyses were used to study the associations between potential risk factors measured in early pregnancy and DRI or pain intensity (worst evening pain) in gestation week 30. Associations between the explanatory variables and each of the response variables as well as between the explanatory variables were studied by Pearson correlation coefficients. The explanatory variables showing a significant relationship with the response variable or found important in previous studies were entered into a multiple linear regression model. The best subsets of explanatory variables were selected through exclusion of the variables with the smallest contribution to the model (the largest p-values). Two

adjusted models were presented for each of the response variables, without (model 1) and with (model 2) adjustment for DRI or pain intensity at inclusion in early pregnancy. Model 2 was also included to examine the risk factors for the change in DRI or pain intensity from early to late pregnancy. The residuals were examined to check model assumptions. Interaction effects between the variables in the models were also tested.

9.7.3 Paper III

Multiple linear regression analyses were used to study the associations between potential risk factors measured in pregnancy and DRI or pain intensity (worst evening pain) measured 12 weeks postpartum. Associations between the explanatory variables and each of the response variables as well as between the explanatory variables were studied by Spearman rank correlation coefficients.

Explanatory variables significantly associated with the response variable or found important in previous studies were entered into a multiple linear regression model. The best subsets of explanatory variables were selected through exclusion of the variables with the smallest contribution to the model (the largest p-values). The residuals were examined to check model assumptions. Interaction effects were tested, but real interactions may go undetected since this test may lack power. [41]

Since a large number of the women reported low pain intensity and low DRI, 12 weeks postpartum, we also repeated the multiple linear regression analyses after transformation (natural logarithms) of both pain intensity and DRI.

In order to estimate the odds ratios for sustained PGP, we categorized the women as recovered or non-recovered 12 weeks postpartum based on a combination of pain and disability. Women were defined as non-recovered if self-reported PGP and/or markings in the pelvic area on the pain drawing were present and if the DRI was above ten points.[83] A logistic regression model was used to study the associations between non-recovery and the same explanatory variables as used in the multiple linear regression analyses. We also used an alternative definition of non-recovery based on the definition described above, but in addition the pain intensity should be above ten on the VAS. The results from the logistic regression model were similar applying the two response variables.

10 MAIN RESULTS

The results are described in detail in each of the papers, hence only a summary of the main results is given here.

10.1 Prevalence of self-reported PGP

The prevalence of self-reported PGP was high at all time points in this study (table 8). Within the entire cohort, 35 % of the women reported PGP at inclusion. At gestation week 30 the prevalence had increased to 62 % followed by a decline to 31 % 12 weeks postpartum. At all three times this was based on the answer on a single question: “Do you have pain in the pelvic area?”

10.2 Disability at gestation week 30 (paper I)

In the cross-sectional study in late pregnancy (gestation week 30) we explored associations between pain locations, responses to clinical tests and disability. Self-reported pain locations were established from pain drawings, in two different ways; distinguishing between PGP and LBP as well as distinguishing between different pain locations in the pelvic area (symphysis pain only, posterior pain only, combined symphysis pain and unilateral posterior pain, combined symphysis pain and bilateral posterior pain). Disability was measured by the Disability Rating Index (DRI).

Large variations in DRI were constantly seen within each of the subgroups based on pain locations, and all subgroups had women reporting DRI below 10 and above 50 points. DRI was significantly associated with pain locations ($p<0.001$). Women with combined pain in the symphysis and bilateral posterior pain scored significantly higher on DRI compared with all other pain locations ($p<0.001$). PGP was more strongly associated with disability than was LBP. No difference in DRI was found between women reporting PGP and women reporting combined PGP and LBP. These results indicate that PGP has a significant impact on disability in pregnancy and that having LBP in addition does not increase the disability.

Women with bilateral positive posterior pelvic pain provocation (P4) test scored significantly higher on DRI than women with unilateral positive P4 and bilateral negative

P4 ($p<0.001$). Furthermore a statistical higher DRI was found in women with active straight leg raise (ASLR) test score >0 compared with ASLR=0 ($p<0.001$).

The multivariable linear regression analyses showed that pain locations in the pelvic area, responses to P4 and ASLR tests, contributed independently and statistically to the variation in DRI ($R^2=0.32$, $p<0.001$) (table 8).

Table 8: Final multiple linear regression model for the associations between the response variable DRI at gestation week 30 and the explanatory variables: pain locations in the pelvic area, P4 and ASLR. The model contributed to 32 % of the variability in DRI.

	Crude estimates		**Adjusted estimates[3]**	
	β[1] (95 % CI[2])	**p-value**	**β[1] (95 % CI[2])**	**p-value**
Pain locations				
No PGP	Reference	<0.001	Reference	<0.001
Symphysis pain only	6.3 (-2.4, 15.1)		4.0 (-4.1, 12.1)	
Posterior pain only	12.1 (6.9, 17.2)		6.8 (1.6, 12.1)	
Combined symphysis pain and unilateral posterior pain	14.7 (6.5, 22.8)		9.7 (1.8, 17.6)	
Combined symphysis pain and bilateral posterior pain	26.5 (20.1, 32.8)		18.0 (11.3, 24.7)	
P4				
Negative	Reference	<0.001	Reference	<0.001
One-sided positive	2.4 (-3.5, 8.4)		-3.2 (-9.0, 2.4)	
Bilateral positive	16.4 (11.9, 21.0)		6.7 (1.8, 11.6)	
ASLR test				
score = 0	Reference	<0.001	Reference	<0.001
score > 0	15.4 (11.1, 19.7)		10.9 (6.7, 14.9)	

[1] Estimated regression coefficients, [2] CI, confidence interval, [3] adjusted for the other variables in the table; DRI, disability rating index; PGP, pelvic girdle pain; P4, posterior pelvic pain provocation test; ASLR, active straight leg raise test

10.3 Risk factors for disability and pain at gestation week 30 (paper II)

Paper II is a longitudinal observational study, following women from early to late pregnancy for the purpose of identifying risk factors for disability and pain in gestation week 30. Disability was measured by DRI and pain intensity (worst evening pain) by VAS, self-reported pain locations in the pelvic area, were established from pain drawings. The clinical examinations included pain provocation tests for PGP as well as the functional ASLR test. Response to the clinical tests, pain locations within the pelvic area (symphysis pain only, posterior pain only and combined symphysis pain and posterior pelvic pain) and previously identified risk factors for PGP were included in the analysis.

Self-reported pain locations in the pelvic area, responses to the P4 test, and sum of positive pain provocation tests in early pregnancy were identified as risk factors for disability and pain intensity in gestation week 30 in a multivariable regression model ($p \leq 0.03$) (table 9). In the model with pain intensity as response variable, the adjusted estimate for bilateral positive P4 test was 15.2 (95 % CI: 5.8, 24.6), thus this CI indicates that the P4 test is of significance even though p=0.07. In addition, distress was a risk factor for disability (p=0.006) but not for pain intensity.

To explore the change in DRI from early pregnancy until gestation week 30, we adjusted for DRI in early pregnancy in the model. This resulted in an increase in the R^2 from 0.26 to 0.37 and the sum of positive pain provocation tests and HSCL-25 were no longer significant (p=0.26 and p=0.49, respectively). To explore the change in pain intensity from early pregnancy until gestation week 30 we adjusted for pain intensity in early pregnancy in the model. This resulted in an increase in the R^2 from 0.29 to 0.33 and the sum of positive pain provocation tests in early pregnancy was no longer significant (p=0.23). Further details are shown in table 4 and 5 in paper II.

Fear avoidance beliefs, a score on the ASLR test of four and above, and number of pain sites in other parts of the body in early pregnancy were not significantly associated with either DRI or pain intensity in gestation week 30.

Table 9: Final multiple linear regression models showing the associations between disability or pain intensity (worst evening pain) in gestation week 30 and risk factors measured in early pregnancy (n=268)

	DRI				Pain intensity			
	Crude estimates		Adjusted estimates[3]		Crude estimates		Adjusted estimates[3]	
	β[1] (95 % CI[2])	p-value	β[1] (95 % CI[2])	p-value	β[1] (95 % CI[2])	p-value	β[1] (95 % CI[2])	p-value
Pain locations								
No pain	Reference	<0.001	Reference	0.007	Reference	<0.001	Reference	<0.001
Symphysis pain only	17.7 (6.8, 28.6)		14.0 (3.7, 24.1)		44.2 (27.7, 60.6)		40.4 (24.4, 56.5)	
Posterior pain only	10.7 (6.2, 15.3)		4.8 (-0.2, 9.6)		23.5 (16.6, 30.3)		15.3 (7.8, 22.8)	
Combined symphysis pain and posterior pain	24.5 (15.6, 33.5)		11.8 (2.6, 21.0)		40.5 (26.9, 54.0)		26.0 (11.6, 40.4)	
P4 test								
Negative	Reference	<0.001	Reference	<0.001	Reference	<0.001	Reference	0.07
Unilateral positive	8.0 (2.6, 13.5)		2.2 (-3.4, 7.9)		16.5 (7.7, 25.2)		5.8 (-3.1, 14.8)	
Bilateral positive	19.8 (14.3, 25.2)		12.0 (6.0, 18.0)		28.6 (19.9, 37.3)		15.2 (5.8, 24.6)	
Sum of positive pain provocation tests	5.3 (3.9, 6.7)	<0.001	1.7 (0.3, 3.0)	0.02	6.3 (4.5, 37.3)	<0.001	2.3 (0.3, 4.4)	0.03
HSCL-25								
<1.75	Reference	<0.001	Reference	0.006	-	-	-	-
≥1.75	14.0 (7.6, 20.3)		8.2 (2.3, 14.0)					

[1] Estimated regression coefficients, [2] CI, confidence interval, [3] adjusted for the other variables in the table. DRI, Disability Rating Index; P4 test, posterior pelvic pain provocation test; HSCL-25, Hopkins Symptom Check List

10.4 Risk factors for disability and pain 12 weeks postpartum (paper III)

Paper III is a longitudinal observational study following women afflicted by PGP from late pregnancy (gestation week 30) until 12 weeks postpartum for the purpose of identifying risk factors for sustained disability and pain 12 weeks postpartum. Disability was measured by DRI and pain intensity by VAS 12 weeks postpartum. We used the same clinical tests as in paper II but the data were taken from the tests performed in gestation week 30. Clinical variables (from gestation week 30) together with previously identified risk factors were included in the analysis.

Based on multivariable linear regression analyses, sum of positive pain provocation tests was a risk factor for both disability and pain intensity 12 weeks postpartum ($0.03 \leq p \leq 0.04$) (table 10). Pre-pregnancy LBP was a risk factor for DRI 12 weeks postpartum ($p=0.03$) and number of pain sites in other parts of the body was a risk factor for pain intensity ($p=0.007$). Pre-pregnancy BMI was also associated with both disability and pain intensity and the response to the ASLR test was associated with disability, though none of them significantly.

In order to estimate odds ratios (OR) for non-recovery from PGP postpartum, we defined women as recovered or non-recovered based on pain locations in the pelvic area and disability. Women were non-recovered if self-reported PGP and/or markings in the pelvic area on the pain drawing were present and if the DRI was above 10. We performed a logistic regression analysis including the same risk factors as described for the linear regression analyses (table 11). The number of pain sites in other parts of the body and sum of positive pain provocation tests were significantly identified as risk factors. The odds increased with increased number of pain sites and OR was 4.4 (95 % CI (1.3, 14.6)) for women with 3-4 pain sites as compared to women with no pain sites in the adjusted analyses. Moreover, OR was 3.5 (95 % CI (1.2, 10.3)) for women with 6-8 positive provocation tests as compared to women with 0-1 positive test. Pre-pregnancy BMI was also associated with non-recovery, though not significantly.

Table 10: Final multiple linear regression analyses showing associations between DRI or pain intensity (worst evening pain) 12 weeks postpartum and risk factors measured in gestation week 30 (n=179).

	DRI				Pain intensity			
	Crude estimates		Adjusted estimates[3]		Crude estimates		Adjusted estimates[3]	
	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value
Pre-pregnancy BMI								
<25 kg/m^2	Reference	0.03	Reference	0.07	Reference	0.02	Reference	0.05
≥25 kg/m^2	5.6 (0.5, 10.6)		4.6 (-0.3, 9.5)		8.8 (1.5, 15.1)		5.7 (-0.3, 11.8)	
Pre-pregnancy LBP								
No	Reference	0.04	Reference	0.03	-	-	-	-
Yes	5.0 (0.3, 9.8)		5.0 (0.5, 9.5)		-		-	
Sum of positive pain provocation tests								
0-1 pos tests	Reference	<0.001	Reference	0.03	Reference	0.006	Reference	0.04
2-3 pos tests	3.4 (-1.7, 10.5)		1.0 (-6.2, 8.3)		5.7 (-4.1, 15.5)		2.3 (-7.4, 11.9)	
4-5 pos tests	-1.7 (-4.8, 8.1)		-0.4 (-6.9, 6.2)		5.4 (-3.5, 14.3)		1.3 (-7.4, 10.1)	
6-8 pos tests	12.0 (5.7, 18.3)		7.7 (1.1, 14.3)		15.1 (6.4, 23.8)		11.2 (2.4, 19.8)	
ASLR test								
Score = 0	Reference	0.005	Reference	0.05	-	-	-	-
Score > 0	7.6 (2.3, 12.9)		5.4 (-0.1, 10.9)		-		-	
Number of pain sites								
0	-	-	-	-	Reference	0.03	Reference	0.007
1	-		-		3.9 (-3.5, 11.4)		1.5 (-5.9, 9.0)	
2	-		-		9.9 (0.4, 19.3)		8.8 (-0.5, 18.2)	
3-4	-		-		21.5 (10.7, 32.3)		18.7 (7.9, 29.6)	

[1] Estimated regression coefficients, [2] CI, confidence interval, [3] Adjusted for the other variables in the table. DRI, Disability Rating Index; BMI, body mass index; LBP, low back pain, ASLR, active straight leg raise

Table 11: Multiple logistic regression analyses showing crude and adjusted odds ratios with 95% confidence intervals for non-recovery 12 weeks postpartum due to pre-pregnancy BMI, number of pain sites and sum of positive pain provocation tests measured in gestation week 30.

	Crude estimates		**Adjusted estimates[3]**	
	β^1 (95% CI[2])	p-value	β^1 (95% CI[2])	p-value
Pre-pregnancy BMI				
<25 kg/m^2	1.0		1.0	
≥25 kg/m^2	2.2 (1.1, 4.4)	0.03	2.1 (1.0, 4.5)	0.05
Number of pain sites				
0	1.0		1.0	
1	2.8 (1.2, 6.2)	0.01	2.3 (1.0, 5.5)	0.05
2	2.3 (0.8, 6.4)	0.1	2.0 (0.7, 5.7)	0.21
3-4	5.2 (1.7, 15.9)	0.004	4.4 (1.3, 14.6)	0.02
Sum of positive pain provocation tests				
0-1 pos tests	1.0		1.0	
2-3 pos tests	1.7 (0.5, 5.5)	0.40	1.2 (0.3, 4.0)	0.82
4-5 pos tests	1.5 (0.5, 4.4)	0.51	1.0 (0.3, 3.3)	0.94
6-8 pos tests	5.0 (1.8, 14.0)	0.002	3.5 (1.2, 10.3)	0.02

[1] Estimated regression coefficients, [2] CI, confidence interval, [3] Adjusted for the other variables in the table; BMI, body mass index

11 GENERAL DISCUSSION

The central aspects in each of the studies have been discussed in the respective papers. The discussion part of this thesis we will concentrate on some important methodological aspects as well as on the discussion of some main issues across the studies.

11.1 Discussion of methodological aspects

11.1.1 Participants and study samples

This thesis is based on a cohort study of women recruited consecutively among Norwegian speaking pregnant women at four MCUs in the Oslo area. Women not expected to have a normal pregnancy (as determined by the midwives) and women in late gestational age were excluded, but no further selections were made in the recruitment procedure. Out of 385 eligible women, 326 women aged 18 – 45 years participated (mean 31.4 years). According to Statistics Norway, the average age for women giving birth in Norway was 30.3 years for the period 2006 – 2008, and women giving birth in Oslo were a bit older than in the rest of the country.[85] Twelve percent of all Norwegian women who had live births in 2008 were single.[85] These numbers suggest that the participants in the cohort may be representative for pregnant women living in urban parts of Norway. Only 15 % (59/385) declined participation in the study, and 8 % (27/326) of the participants dropped out during the study period (13 of these, 50 %, withdrew due to a miscarriage). We evaluated the characteristics of the women in the cohort to be similar to the women who declined participation (table 5 page 37). Furthermore the differences between the groups of women selected and used in the analyses in the different studies are also slight. The similarities of the samples and the non-participants suggest that our samples were comparable.

Our intention was to include pregnant women early in pregnancy, before PGP was present. Based on information from the MCUs we expected most women to register between gestation week 12 and 18. Although some women registered earlier and others later than we expected; we decided not to change our protocol. Instead, the women included later than gestation week 20 were excluded from the analyses in paper II (risk factors for development of disability and pain). Since we were concerned about the effect of the broad gestation age interval at inclusion, we also controlled for the effect of gestation week at

inclusion in the analyses. As described in the results in paper II, we found that gestation week at inclusion had no significant effects.

11.1.2 Design

The results presented in this thesis are based upon self-reported (subjective) data and clinical (objective) data collected two times in pregnancy (at inclusion in early pregnancy and in gestation week 30) and one time after delivery (12 weeks postpartum). A prospective design (used in paper II and III) is needed to be able to examine risk factors for development of a condition (PGP). A cross-sectional design (as used in paper I) has some limitations concerning the opportunity to draw conclusions.[20] Since all data are collected at the same time, it is not possible to conclude whether exposure or response came first, and no conclusions about cause-effect relationships can be drawn. However, this design was satisfactory in paper I since the purpose was to study associations among different factors measured at the same time.

Multivariable regression analyses were used to explore associations between the potential risk factors and the response variables and to estimate the explanatory power of the different risk factors. Using multivariable analyses, as opposed to bivariate analyses, makes it possible to identify and control for effects from other variables, i.e. confounding effects and interactions.[6] When we compare our results with previous studies, we see that most of the previously identified risk factors were not significantly associated with the response variables when using multivariable models (except pre-pregnancy LBP and pre-pregnancy BMI). This may be because the clinical variables absorb the effect of other variables. Hence, some of the explanation for the different results compared with previous studies could be the use of a different design, clinical explanatory variables, different response variables (discussed further also in chapter 11.1.3), and statistical methods.

Blinding procedures are recommended and important in research to avoid bias from awareness.[76] The physiotherapists performing the examinations in the present cohort study were not given access to any information about the women until after the examination. The women were examined independent of the presence or absence of PGP. This design is different from previous studies which often have examined only the women presenting with pain.[8;33;48] Furthermore, no predefined classifications were used in the clinical examinations in this thesis. This means that the tests were performed and the responses recorded without including any clinical rationale, and without any attempts to establish a diagnosis. The

examinations were done for research purposes and these procedures increase the quality of the data gathered from the tests. Hence the examination-procedure differs from ordinary clinical practice. Nevertheless, this procedure provided opportunities to use the responses to clinical tests both as single data as well as different independent clusters or sum scores in the analyses.

We selected women for examination in gestation week 30 based on a simple questionnaire concerning pain in the pelvic and/or low back area in gestation week 28. A small group of women (9 %) were not selected for further clinical examinations. However, all women in the cohort were included in the prevalence estimates based on self-reports at each time point, but in the analyses using data from clinical examination at gestation week 30 this group of women could not be included since they were examined only once (at inclusion). The close similarity in the entire sample of 326 participants, and the sample used for the different analyses and papers (table 5, page 37) suggest that the selection has not caused a large bias.

A large fraction of the women without PGP, but also several with PGP scored low on both disability (DRI) and pain intensity 12 weeks post partum; hence the data were skewed. We controlled for this effect in two ways (paper III): by repeating the multiple linear regression analyses with pain intensity ln transformed and DRI ln transformed as well as by using logistic regression analyses and a constructed response variable for non-recovery based on both pain and DRI. The results were similar for all approaches and this indicates that the results are robust and trustworthy.

The sum of positive pain provocation tests was identified as a risk factor for disability and pain in both gestation week 30 and 12 weeks postpartum. The variable was used differently in the analyses at the two times; in the analyses in paper II, it was used as a continuous variable, and in paper III it was used as a categorical variable. The results in paper III showed that the largest effect was when 6-8 tests were positive. In retrospect, therefore we see that this variable probably should have been used as categorical variable also in paper II.

The ASLR test was used with different cut-off values in the papers in this thesis. Initially we intended to use a cut-off in the ASLR score that distinguished between women with strong affliction and those without or lesser affliction. Hence we evaluated the previously proposed cut-off value of one to be too low.[56] In both paper I and II we therefore decided to use a cut-off of four and above for the afflicted group, as also used as an inclusion criterion in the RCT by Stuge and co-workers.[88] In the revision process on paper I

we were asked by the reviewers to change this cut-off to one, in accordance with the original work by Mens and co-workers.[56] This was done and did not change the initial results of paper I. The revision process for paper II was ongoing in parallel with paper I, and the cut-off was not changed in paper II. In retrospect, we see that this probably could have been done for the consistency of the papers, although a change would implicate a less strict criterion for the afflicted group. Additional analyses have been performed to enable a discussion of the implications of using the different cut-off values. The results are presented and discussed in chapter 11.2.4.

11.1.3 PGP and measures of affliction

Several studies have used self-reported PGP (yes/no) as an outcome measure.[45;62;67;68;80] Two main elements are included in the definition of PGP from the European Guideline group; the location of pain and the reduced endurance in conjunction with weight bearing activities.[106] Hence both pain and function are evaluated as important for the condition. These elements are also assessed and evaluated in the clinical examination of PGP patients. In previous studies PGP has been regarded as both a normal discomfort during pregnancy,[24;68] and a severe and disabling problem.[13] Hence the view on affliction from PGP seems to vary. Since we believe that affliction cannot be described based on a yes/no question, we included two measures for the degree of affliction in the current papers; disability (DRI) and pain intensity (worst evening pain, measured by VAS). Both variables are continuous and are intended to provide more graded information about affliction than merely presence or absence of PGP. Although the use of graded scales has been recommended,[18] it has not been used in studies examining PGP in pregnancy before.

The response variables used in the present studies are all subjective, however in different ways. A yes/no response to the question about presence of PGP is highly dependent on the women's own evaluation of the pain as well as the location of pain and is probably also culturally influenced. As for the presence or absence of PGP, also the graded scales are self-reported and thus subjective. Pain intensity (measured by VAS) is a subjective phenomenon quantifying the pain. DRI surveys the difficulties in performing specific activities; hence it is the degree of difficulty that is assessed. The nature of pain makes objective measurement of intensity impossible,[11] but it is possible that disability could have been measured more directly. To our knowledge, no such specific disability measurement for use in pregnant women exists. The only functional test specifically aimed

at PGP is the ASLR test which has been found to discriminate between PGP patients and healthy subjects.[56] Furthermore difficulties in performing the ASLR has presently shown to be associated with increased mobility in the pelvic joints as well as disease severity in PGP patients.[57;58] Strong associations between ASLR and DRI were found in the cross-sectional study in paper I. This finding suggests that the impairments assessed by ASLR are closely related to limitations in activities as reflected by DRI when measured at the same time.[29]

Pain is often characterized by the assessment of location, intensity, and temporal aspects.[11] These assessments are used in both research and clinical practice. The women with PGP in the present cohort study reported large individual variations of pain intensity. This is in accordance with a recently published review on differences in pain sensitivity by Nielsen and co-workers,[64] saying that "even though some conditions may be more painful than others, the variation between individuals with the same condition is far greater than the difference in painfulness across conditions". Patients may experience pain differently, and even with the same injury some may not report any pain at all.[103] It still seems important to measure the women's own perception of pain.

Several instruments have been developed and used to assess pain intensity.[11] The visual analogue scale (VAS), as used in the present thesis, is often used for assessing worst, least, or average pain over the past 24 hours or during the past week. The measure of pain intensity can probably be seen as even more subjective and less calibrated than DRI. Furthermore, disability is said to be one of the most substantial consequences of pain.[103] The latter can explain the strong correlation between pain intensity and DRI seen in both gestation week 30 and 12 weeks postpartum.

We have argued for the use of graded scales in this thesis, since PGP can be present with little affliction. Yet, we have also used dichotomous variables and estimated the odds-ratios for sustained PGP 12 weeks postpartum among women afflicted from PGP in pregnancy (paper III). We used two dichotomous variables, based on presence of PGP and a degree of disability to:

1. define women afflicted from PGP in gestation week 30
2. define non-recovered women 12 weeks postpartum.

We used the graded scales to standardize afflicted women in late pregnancy and non-recovered women postpartum, respectively. Since our data showed that pregnancy influenced DRI, we used a cut-off value on disability above the effect of pregnancy itself to estimate a main effect of PGP in gestation week 30. Furthermore, women without affliction

postpartum should report disability comparable with healthy women. In the study from Salèn and co-workers,[83] almost none of the healthy individuals scored above ten (median DRI was 0.8, IQR 4.7 for healthy individuals with no disability, and median DRI was 8.7, IQR 15.4 for healthy individuals with minor ailments). The described procedure, used in paper III, differs from what has been done before, since most previous studies have used presence of PGP as a criterion.[2;10;13;61;70;73;82;95;96] It could be discussed to what extent our definition of non-recovered women is adequate for identification of those with sustained PGP. This can only be tested by analyses in later follow-ups. However, the mean DRI and pain intensity of this group were 30 (IQR 25) and 34 (IQR 47) respectively and indicate that they had a relatively high affliction compared with healthy women and other patient groups.[83]

The need for measurement tools specially designed for pregnancy-related PGP has been discussed and the European Guideline group concluded that: "Future studies should therefore address the challenge of developing suitable outcome measures to assess the functional status for PGP."[106] However, the use of established measurement tools seems important in order to be able to compare results between different studies and also between different patient groups and healthy individuals. The DRI as a measure of disability, has been used in different studies, and comparison could be made between this cohort and a Swedish cohort of pregnant women,[67] as well as with healthy women of the same age and patient groups.[83]

11.1.4 Clinical examinations and tests

Different studies have used different tests in their assessment, mostly for establishing the diagnosis of PGP, and have not examined the responses to the tests as potential risk factors. The ideal clinical test has high levels of reliability, sensitivity and specificity. A common internal validity concern is connected to the clinimetric properties of the clinical tests. The reliability and validity for tests used for examining pain in the pelvic area have shown large variations.[50;77;79;86;97;98] We selected mainly pain provocation tests for this thesis. A recently published study has also shown that reliability and validity for single pain provocation tests as well as composite of tests were good when injections procedures in the SIJ and adjacent structures were used.[52] As mentioned before, the relationship between SIJ and PGP is unclear and the validity of the tests used for PGP can still be questioned. In a previous study we evaluated four of the actual pain provocation tests (distraction test, compression test, P4

and Patrick-Faber), and found the reliability to be moderate to good.[79] However, when it comes to validity, there are more uncertainties concerning structures responsive for the pain, and thus the lack of a diagnostic reference standard is obvious and could be problematic.

Even though there are uncertainties concerning the clinimetric properties of the clinical tests, we believe that we have selected relevant tests and optimized the performance and interpretation of the results. Furthermore, the identification of responses to clinical tests as risk factors for PGP has not been studied previously.

11.2 Discussion of results

11.2.1 Prevalence of PGP

Prior to the data collection for the present study, a population based retrospective questionnaire study was carried out.[80] This included 1,817 women from two communities just outside Oslo, recruited in 1998-99, and the prevalence of PGP was 46%. It was our hypothesis that this high prevalence could be partly due to recall bias and that lower values would be found in a prospective design. However, the self-reported prevalence in the present cohort study was 35% and 62% in early and late pregnancy, respectively. Hence, the prevalence in the retrospective study was probably not an overestimation caused by the study design. On the opposite, our data seems to indicate even higher prevalence. Several factors may have contributed to this fact. Like in several other studies, the estimates of the prevalence are based on self-reported presence or absence of the condition.[22;45;55;62;67;68] For the prevalence estimates we used the answer from a simple question in the present thesis: "Do you have pain in the pelvic area?" (Yes/no). Hence, the response depends on the women's individual understanding of the concept and the influence of the cultural environment. The high prevalence could be due to the fact that the social and medical acceptances of PGP have increased in Norway during the last 15 – 20 years, and that the focus on PGP has increased.[22;43] The prevalence is, however, in accordance with recently published studies in other countries.[35;62;63;67] The large prevalence numbers could also indicate that the threshold for reporting PGP was low. It could also be a risk for over reporting PGP due to the focus of being participants in a study. We have tried to limit the over-reporting by reducing the focus on PGP both in the questionnaires and in the information (oral and written) given to the women.

11.2.2 Disability in pregnancy – a normal or pathological response?

In clinical practice, it is a common belief that in pregnant women with PGP the physical disability during pregnancy is caused by PGP. However, it seems reasonable that pregnancy in itself might also cause disability, since pregnancy induces great bodily changes in the women. The increase in body weight and change of body posture may impact on physical function. A comparison of DRI scores for women with and without PGP in this study could give a picture of the pregnancy effect on disability (figure 15). The DRI values of the women without PGP 12 weeks postpartum (the only non-pregnant data-set) are low and

exhibit a rather narrow range. These scores are comparable with DRI from healthy women of approximately the same age,[83] and this suggests that most of the women are not afflicted by disability 12 weeks postpartum. Comparing these values with the DRI scores at inclusion for women without PGP can possibly show the pregnancy effect on disability, already present in early pregnancy. The increase in disability in women with PGP at inclusion, compared with women without PGP, is the additive effect from PGP in early pregnancy, also shown previously.[67] Furthermore, an increase in disability is seen from inclusion until gestation week 30 in women with and without PGP. However, the women with PGP have more disability than women without PGP.

The median DRI score in gestation week 30 among women with PGP in the present cohort was 44 (IQR 26.7), and thus comparable (but with somewhat larger variation) with scores from patients with other musculoskeletal disorders classified with mild-to-moderate disability. In the study from Salèn and co-workers a combined group of patients with neck, shoulder, or LBP (all classified with mild-to-moderate disability) scored 39 (IQR 19.5) points on DRI.[83]

There is a possibility that the multiple linear regression models could have identified risk factors within a small range of the continuous response variables. The response variable used in the logistic regression model distinguished between women with negligible disability and women with a certain level of disability. Since the clinical risk factors were identified also in the logistic regression model this strengthens our results.

In the present cohort the range of DRI is higher among women with PGP at all three times compared with women without pain. This finding indicates a wide variation in affliction when PGP is present. Mean DRI 12 weeks postpartum among women with PGP was low (20) in this cohort, indicating low functional impairment postpartum even when pain is present. Corresponding value of DRI among the women included in the RCT three months postpartum from Stuge and co-workers was 54.[87] Only about 7 % of the women in the present cohort sought treatment postpartum, and this might explain the low DRI compared with the women included in the RCT.

The mean pain intensity due to PGP 12 weeks postpartum was also low, and lower than reported at inclusion. This shows that women with PGP in this cohort have more pain in early pregnancy than 12 weeks postpartum.

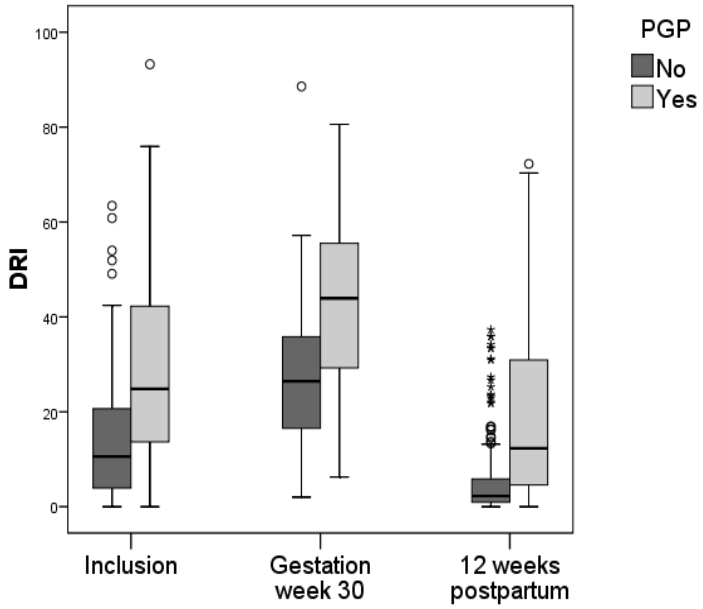
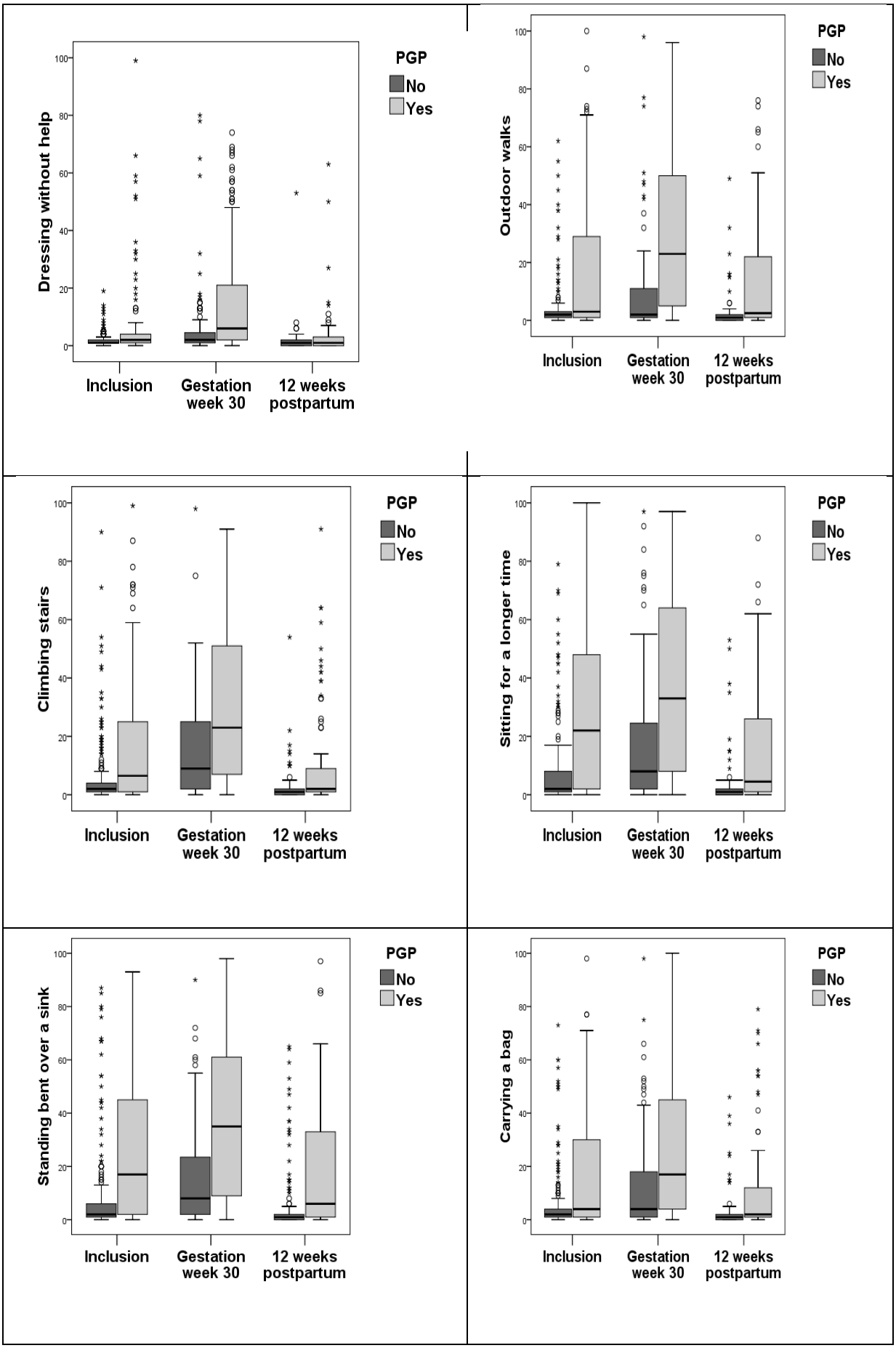


Figure 15: Box-plot showing the effect of pregnancy on DRI at inclusion, gestation week 30 and 12 weeks postpartum. Data is given for the whole cohort (n=326) split according to presence or absence of PGP at the three times. Median, quartiles and range are shown. Circles show outliers (>1.5 IQR above the 75th percentile) Asterisks show extreme values (>3 IQR above the 75th percentile)

When studying the single items in DRI (figure 16), one sees almost the same patterns as for the summarized DRI scores (figure 15). Women with PGP tend to score higher at all three times compared with women without PGP, which means they report more functional impairment than women without PGP. The exception is in the item "dressing without help" where a "floor effect" is seen, implying that this is not a problem for the women in this cohort.

For the items "running", "doing heavy work", "lifting heavy objects" and "participating in exercise/sports" we see that at 12 weeks postpartum the women with PGP score higher on these items and the range was wider in comparison with the rest of the items. During pregnancy there is also a higher effect from both pregnancy and PGP on these items compared with the other items. This confirms that several pregnant women have difficulties with strenuous activities, but this is common for women both with and without PGP. These findings do not disqualify the use of DRI on pregnant women.


Dressing without help
Outdoor walks
Climbing stairs
Sitting for a longer time
Standing bent over a sink
Carrying a bag
PGP
No
Yes
Inclusion
Gestation week 30
12 weeks postpartum

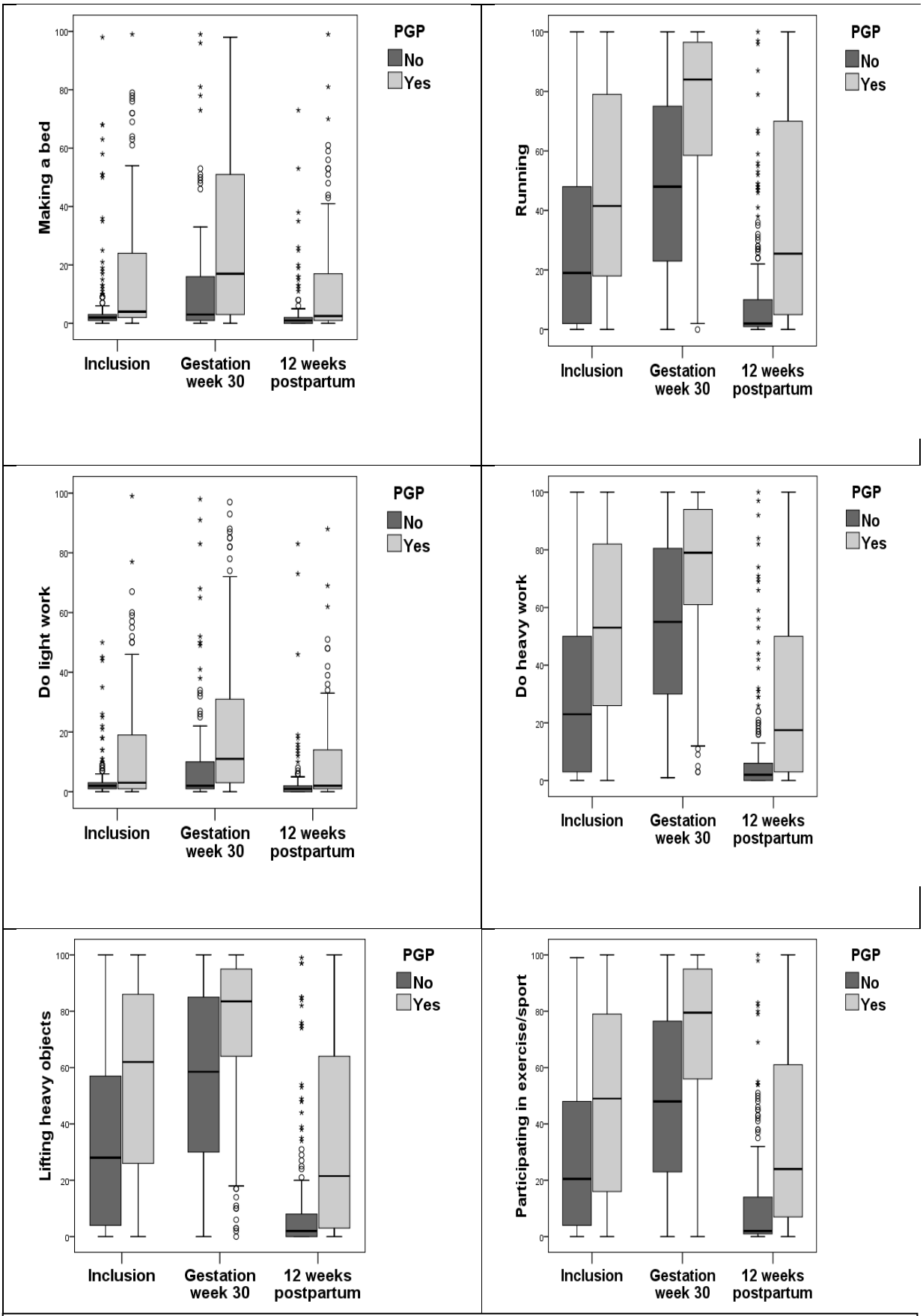


Figure 16: Box-plot of the single items in DRI at the three time points. Data is given for the whole cohort (n=326) split according to presence or absence of PGP. Median, quartiles and range are shown. Circles show outliers (>1.5 IQR above the 75th percentile) Asterisks show extreme values (>3 IQR above the 75th percentile)

11.2.3 Risk factors for development of PGP and sustained PGP postpartum (papers II-III)

The risk factors for development of disability and pain intensity in late pregnancy and the risk factors for sustained disability and pain intensity 12 weeks postpartum are shown in table 12.

Table 12: Risk factors for development and prolongation of PGP during and after pregnancy

	Response variables	
	Disability	Pain intensity
Risk factors for development of PGP during pregnancy **(Paper II)**	Pain locations within the pelvic area P4 test Sum of positive pain provocation tests Distress (HSCL)	Pain locations within the pelvic area P4 test Sum of positive pain provocation tests
Risk factors for sustained PGP postpartum **(Paper III)**	Sum of positive pain provocation tests ASLR test* Pre-pregnancy LBP Pre-pregnancy BMI*	Sum of positive pain provocation tests Number of pain sites in other parts of the body Pre-pregnancy BMI*

*associations but not significant

PGP, pelvic girdle pain; P4, posterior pelvic pain provocation; HSCL, Hopkins symptom check list; ASLR, active straight leg raise; LBP, low back pain; BMI, body mass index.

To our knowledge, this study is the first prospective cohort study to identify clinical risk factors (pain locations within the pelvic area, responses to clinical tests) while controlling for socio-demographical and psychological factors. Most of the factors identified

as risk factors in previous studies (e.g. age, parity, and strenuous work conditions) were not associated with the response variables when using multivariable analyses. This may indicate that the clinical factors are stronger and absorb the effect of most of the socio-demographical and psychological variables. Furthermore, previous studies have often recorded risk factors retrospectively in late pregnancy after the onset of symptoms of PGP.[4;62] These factors could be biased by the presence of pain.[60] The use of a prospective design and recording of possible risk factors early in pregnancy (paper II) before onset of symptoms or before the symptoms were defined as a problem, reduced this bias.

The effect estimates are large for the clinical risk factors, and in both gestation week 30 and also 12 weeks postpartum the estimates for pain intensity seems to be higher than for DRI (table 9, page 54 and table 10, page 56). For instance our data (gestation week 30) shows that pain intensity in late pregnancy is 40.4 points higher (95 % CI: 24.4, 56.6) when pain was present in the symphysis only, compared with having no pain in early pregnancy and adjusted for positive response to the P4 test and the sum of positive pain provocation tests. Even though the confidence intervals are large, the associations between clinical risk factors and effects of PGP seem to be strong. These results could be of importance in clinical practice, since the same information is collected and used for decision making and selection of treatment modalities.

Interestingly, we identified different risk factors for disability and pain in gestation week 30 than 12 weeks postpartum (table 12). However, the sum of positive pain provocation tests is consistent for both response variables at both times (gestation week 30 and 12 weeks postpartum).

Pain locations in the pelvic area reported in early pregnancy were risk factors for both disability and pain in gestation week 30 but pain locations in gestation week 30 were not risk factors for any of the responses 12 weeks postpartum. This is surprising, and also in contrast to what has been reported earlier.[2;36] Albert and co-workers reported that combined pain in symphysis and bilateral posterior pain in late pregnancy was a risk factor for non-recovery 2 years postpartum.[2] However, only bivariate associations were examined. Gutke and co-workers reported that combined PGP/LBP in pregnancy was a risk factor for pain 3 months postpartum.[36] It could be that the responses to the clinical tests identified as risk factors in the present studies absorbed some of the effect from pain locations. The results from paper I, where the P4 and ASLR tests were associated with pain locations in gestation week 30 could support this assumption.

Most of the clinical risk factors can be seen as condition specific, while pre-pregnancy LBP, distress and pre-pregnancy BMI are more general and also reported in relation to both PGP and LBP before.[10;28;61;70;82;94-96]

Surprisingly none of the psychological factors, except for distress, were identified as risk factors for either disability or pain in late pregnancy or postpartum. This is in contrast to studies where psychological factors and emotional distress have been shown as important factors for non-recovery of acute LBP.[28;30;31] Fear avoidance beliefs were not identified as risk factor for either disability or pain intensity in the present study. This finding is in contrast to what has previously been reported for acute LBP and could support the need for differentiating between LBP and PGP. [35;42;75] In a recent study, Olsson and co-workers found that women with pain in early pregnancy reported significantly higher levels of fear avoidance beliefs than women without pain.[66] However, the study was cross-sectional and did not examine risk factors for PGP. The present study reports recovered /non-recovered three months postpartum. It is possible that a longer follow-up period may reveal effects of psychological factors.

The number of pain sites in other parts of the body in gestation week 30 was a risk factor for pain intensity 12 weeks postpartum and pain intensity was almost 19 mm higher (95 % CI: 7.9, 29.6) when 3-4 pain sites in other parts of the body were present compared with having no pain sites and adjusted for the sum of positive pain provocation tests and pre-pregnancy BMI (table 10, page 56). This is in accordance with a prospective study on LBP showing that widespread pain was a risk factor for persisting LBP,[94] even though the variables are not completely comparable.

11.2.4 Measurement scales used in different ways

The response to the ASLR test was associated with both disability and pain in the cross-sectional study (paper I), but it was not a risk factor for development of PGP (paper II). As explained in chapter 11.1.2, different cut-off values were used in the paper in this thesis. We repeated the analyses in paper II with a cut-off value of one (instead of four) for the ASLR score, and the results show that ASLR with the low cut off has a significant effect for both DRI and pain intensity as response variables (Tab 13). The effects remain for the risk factors identified in paper II. The only exception is for the sum of positive pain provocation tests which is no longer a significant risk factor for pain intensity. Hence, when used with a cut-off on one, the response to ASLR test in early pregnancy is identified as a risk factor for both disability and pain intensity in gestation week 30. When the ASLR test is used with a

distinction between women with a strong affliction and those with less or no affliction, as shown in paper II, the ASLR was not a risk factor for either disability or pain intensity ($0.53 \leq p \leq 0.71$). One possible explanation for the difference in results might be due to a smaller number of women with a positive ASLR test when using the higher cut off value (n=28 vs. n=110), and thus a lower power. Alternatively, there might be fundamental differences between the phenomena studied when using different score levels of the ASLR.

We also repeated the analyses in paper II with sum of positive pain provocation tests as a categorical variable (0-1, 2-3, 4-5 and 6-8 positive tests) as done in paper III. This analysis resulted in a significant effect of only 4-5 positive tests. Since there was only 12 women with 6-8 positive tests, the power of the test for this group was low and possibly of importance for the non-significant result.

The differences of results when using the scales in different ways show that there is a need for more research on these clinical measures.

Table 13 Adjusted estimates for DRI and Pain intensity with two different levels of cut-off on the score of the ASLR test.

	DRI				Pain intensity			
	Adjusted estimates[3]				Adjusted estimates[3]			
	With ASLR score on four and above *		With ASLR score on one and above		With ASLR score on four and above*		With ASLR score on one and above	
	β[1] (95 % CI[2])	p-value	β[1] (95 % CI[2])	p-value	β[1] (95 % CI[2])	p-value	β[1] (95 % CI[2])	p-value
Pain locations								
No pain	Reference	0.007	Reference	0.01	Reference	<0.001	Reference	<0.001
Symphysis pain only	14.0 (3.7, 24.1)		12.4 (2.1, 22.6)		40.4 (24.4, 56.5)		37.2 (21.1, 53.3)	
Posterior pain only	4.8 (-0.2, 9.6)		4.4 (-0.4, 9.2)		15.3 (7.8, 22.8)		14.7 (7.2, 22.1)	
Combined symphysis pain and posterior pain	11.8 (2.6, 21.0)		11.7 (2.6, 20.8)		26.0 (11.6, 40.4)		25.1 (10.9, 39.4)	
P4 test								
Negative	Reference	<0.001	Reference	0.001	Reference	0.07	Reference	0.02
Unilateral positive	2.2 (-3.4, 7.9)		2.4 (-3.3, 8.0)		5.8 (-3.1, 14.8)		6.1 (-2.8, 15.0)	
Bilateral positive	12.0 (6.0, 18.0)		11.2 (5.1, 17.2)		15.2 (5.8, 24.6)		13.6 (4.2, 23.0)	
Sum of positive pain provocation tests	1.7 (0.3, 3.0)	0.02	1.4 (0.04, 2.7)	0.04	2.3 (0.3, 4.4)	0.03	1.7 (-0.4, 3.8)	0.1
HSCL-25 <1.75	Reference	0.006	Reference	0.04	-	-	-	-
≥1.75	8.2 (2.3, 14.0)		6.4 (0.4, 12.5)		-	-	-	-
ASLR 0	-		Reference	0.04	-	-	Reference	0.01
>0	-		4.7 (0.1, 9.3)		-	-	8.7 (1.8, 15.6)	

* As presented in paper II

[1] Estimated regression coefficients, [2] CI, confidence interval, [3] Adjusted for the other variables in the table. DRI, Disability Rating Index; P4, posterior pain provocation; HSCL, Hopkins symptom check list; ASLR, active straight leg raise.

12 CONCLUSIONS

The following conclusions can be drawn from the work in this thesis:

- There is a high prevalence of PGP during and after pregnancy
- Disability is increased in late pregnancy but a large variation is seen among both the women with and without PGP
- PGP has an additive effect on disability in pregnancy
- In late pregnancy there is an association between pain locations in the pelvic area, responses to the posterior pelvic pain provocation test, P4, and the functional ASLR tests and disability (DRI)
- Pain locations in the pelvic area and responses to the P4 test measured in early pregnancy were risk factors for increased disability (DRI) and pain intensity reported in gestation week 30 (in addition, distress was a risk factor for DRI)
- Sum of positive pain provocation tests (measured in gestation week 30) and pre-pregnancy LBP were risk factors for sustained disability (DRI) 12 weeks postpartum
- Sum of positive pain provocation tests and number of pain sites in other parts of the body (measured in gestation week 30) were risk factors for sustained pain intensity 12 weeks postpartum

The high prevalence of PGP during and after pregnancy indicates that there is a need for attention by health care providers. The large variation in disability at all times regardless of presence or absence of PGP shows that pregnancy itself has an impact on function. Furthermore the results confirm the clinical experience that women with PGP report large variation in affliction. The identification of clinical risk factors for PGP is a novel finding and probably of importance for further development of treatment and prevention strategies.

13 CLINICAL IMPLICATIONS AND FURTHER RESEARCH

The novel finding and main importance of this thesis is the identification of clinical risk factors for PGP. These clinical risk factors may provide a basis for developing targeted prevention and treatment strategies for PGP and thereby potentially reduce the numbers of women with PGP during and after pregnancy. About ⅓ of the women in the present cohort reported to have PGP 12 weeks postpartum, although several with low disability. From the studies in this thesis we do not know how many of these will recover over the subsequent months. It will be of interest to examine whether the clinical factors also represent a risk for pain and disability one year postpartum.

We have identified new clinical risk factors, responses to clinical tests and pain locations within the pelvic area. The next step would be to perform a prediction study, where the effect of the identified risk factors is studied, to confirm their suitability as predictors for PGP.

14 EPILOG

This thesis began with initial questions concerning PGP, previous research and certain unanswered issues. Through the work done in conjunction to the present thesis, it does appear that some of these issues have been partially answered and new knowledge has been acquired.

The results from the studies confirm that the prevalence of PGP is high, even when examined in a prospective design. Since more than 60 % of the pregnant women reported having pain in the pelvic area, this probably indicates that some pain and discomfort in this area during pregnancy is normal. The broad variation in affliction implies that the effect of the pain also varies to a great extent. We have documented that pregnancy itself has an effect on disability and that PGP gives an additive effect. Furthermore, we see that the use of graded scales as outcome measures has been valuable because it provides information about affliction. The results indicate that the degree of affliction should be focused upon in addition to the presence of PGP, in research as well as in clinical work. Focus on affliction may be helpful in developing priority strategies. Identification of clinical predictors may offer possibilities for developing new treatment strategies. The latter implies further research on treatment for PGP.

Reference list

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PAPER I

Hilde Stendal Robinson, Anne Marit Mengshoel, Elisabeth K Bjelland, Nina K Vøllestad.

Pelvic girdle pain, clinical tests and disability in late pregnancy

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PAPER II

Hilde Stendal Robinson, Marit B Veierød, Anne Marit Mengshoel, Nina K Vøllestad.

Pelvic girdle pain – associations between risk factors in early pregnancy and disability or pain intensity in late pregnancy: a prospective cohort study

BMC Musculoskeletal disorders, 2010

Pelvic girdle pain – associations between risk factors in early pregnancy and disability or pain intensity in late pregnancy: a prospective cohort study

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Abstract

Background

Recent studies have shown high prevalence rates for pelvic girdle pain (PGP) in pregnancy. Some risk factors for developing PGP have been suggested, but the evidence is weak. Furthermore there is almost no data on how findings from clinical examinations are related to subsequent PGP. The main purpose for this study was to study the associations between socio-demographical, psychological and clinical factors measured at inclusion in early pregnancy and disability or pain intensity in gestation week 30.

Methods

This is a prospective cohort study following women from early to late pregnancy. Eligible women were recruited at their first attendance at the maternity care unit. 268 pregnant women answered questionnaires and underwent clinical examinations in early pregnancy and in gestation week 30. We used scores on disability and pain intensity in gestation week 30 as outcome measures to capture the affliction level of PGP. Multiple linear regression analysis was used to study the associations between potential risk factors measured in early pregnancy and disability or pain intensity in gestation week 30.

Results

Self-reported pain locations in the pelvis, positive posterior pelvic pain provocation (P4) test and a sum of pain provocation tests in early pregnancy were significantly associated with disability and pain intensity in gestation week 30 in a multivariable statistic model. In addition, distress was significantly associated with disability. The functional active straight leg raise (ASLR) test, fear avoidance beliefs and the number of pain sites were not significantly associated with either disability or pain intensity.

Conclusions

The results suggest that a clinical examination, including a few tests, performed in early pregnancy may identify women at risk of a more severe PGP late in pregnancy. The identification of clinical risk factors may provide a foundation for development of targeted prevention strategies.

Pelvic girdle pain – associations between risk factors in early pregnancy and disability or pain intensity in late pregnancy: a prospective cohort study

Background

Pelvic girdle pain (PGP) is common in pregnancy. Recent studies have shown that about 33-50% of pregnant women report PGP before 20 weeks of gestation, and that the prevalence may reach 60-70% in late pregnancy [1-3]. Despite these high prevalence estimates, we have little knowledge about the risk factors for PGP in pregnancy. Previous studies have reported that strenuous work, a pre-pregnancy history of low back pain (LBP), previous PGP, and multipara are associated with PGP in pregnancy [4-9]. Associations between PGP and psychological variables such as catastrophizing, fear-avoidance beliefs and distress have also been reported [8,10]. However, the number of studies are limited and often hampered by either being retrospective or cross-sectional [7,8], or by lack of multivariable analyses in the prospective studies [4-6].

Moreover, the response variables used in previous studies have most often been dichotomous, such as presence of PGP or not, and did not necessarily reflect the severity of the condition. The importance of also using graded scales has recently been pointed out by Croft [11]. In a recent cross-sectional study we used graded scales and showed that women with combined symphysis pain and bilateral posterior pelvic pain in late pregnancy reported more disability than women with fewer pain sites in the pelvis [3]. Others have shown that women with this combination of pain locations were also less likely to recover postpartum than those with more limited pain distribution [12,13].

Clinical management would probably benefit from an early identification of women at risk for developing disabling symptoms later in pregnancy. A number of tests for pain provocation of different tissues and locations in the pelvis are commonly used and

recommended [14]. Although both pain provocation tests and functional tests have most often been used for diagnostic purposes [13,15-17], they might also detect processes at an early stage. Previous studies of PGP during and after pregnancy have reported that positive scores on the posterior pelvic pain provocation (P4) test and the functional Active Straight Leg Raise (ASLR) test were associated with disability [3,18,19] and pain [16,18,19]. Furthermore, when blinded assessors were used, relative high frequencies of positive responses to the tests were also reported for pregnant women without pain in the pelvic area [3] . These results could either indicate low specificity or alternatively that the tests could detect subclinical afflictions and thus be valuable in early identification of those at risk for more severe afflictions.

We established a cohort of pregnant women to study the associations between socio-demographical, psychological and clinical factors measured at inclusion in early pregnancy and disability or pain intensity in gestation week 30.

Methods

This is a prospective cohort study following pregnant women in Norway from early pregnancy to gestation week 30.

Procedure

The Norwegian public health system offers all women free health services during pregnancy and most women seek special maternity care units (MCUs) for this purpose. We collaborated with four public MCUs in this study, one was located in central Oslo (capital, about 580 000 inhabitants), and the other three covered one entire community (about 24 000 inhabitants) just outside Oslo. Eligible participants were Norwegian-speaking women, who registered at these four MCUs between January 2006 and June 2007. Women not expected to have a normal pregnancy (as determined by the midwives) were excluded. Out of 385 eligible women, 326

gave their informed consent for participation. Out of these 326 women, 280 were included before they reached 20 weeks of gestation, and were thus defined as being in early pregnancy (figure 1). From the time of inclusion to gestation week 30, there were 3 drop-outs and 9 miscarriages among the 280 women included early, thus 268 women participated in gestation week 30 and these constituted our study sample.

After inclusion all answered a comprehensive questionnaire assessing sociodemographic variables, pain locations, pain intensity and disability, distress, and fear-avoidance beliefs. The questionnaire also included questions on general health, health-related quality of life, health locus of control, use of contraceptives, other complaints, and physical activities, variables that were not used in this part of the study. The registered gestation week refers to the week the women were included to the study and completed the questionnaire.

All women were clinically examined in early pregnancy by one of two physiotherapists with post-gradual education in manual therapy. This examination was performed as closely to the inclusion date as possible. Mean time difference between answering the questionnaire and being examined was 1.1 week (SD 1.7 weeks). The clinical examination included six pain provocation tests for the pelvic joints as well as the functional ASLR test and Beighton score for hyper mobility. Other clinical tests were also included, but were not used in this part of the study. The examiner was blinded for all questionnaire data. In gestation week 30, the women filled in a new questionnaire assessing the same elements as at inclusion and underwent a corresponding clinical examination. Data from the clinical examination in gestation week 30 was not used in this part of the study. The Regional Committee for Medical Research Ethics and the Norwegian Social Science Data Services gave formal approval for the study.

Measurements of response variables

Disability and pain intensity were obtained from questionnaire data collected in gestation week 30. Disability was measured by the Disability Rating Index (DRI), consisting of twelve visual analogue scales (VAS) measuring the ability to perform activities of daily living [20]. The scales ranged from 0 – 100 mm, where the end points were "ability to perform activity without restriction" and "inability to perform the activity", respectively. The twelve activities were: dressing without help, outdoor walks, climbing stairs, sitting for a longer time, standing bent over a sink, carrying a bag, making a bed, running, do light work, do heavy work, lifting heavy objects, participating in exercise/sport. DRI was calculated as the mean of the twelve scales. In order to allow the assessment of disability in women with and without PGP, we chose DRI because it measures disability by limitations in daily activities independent of pain. DRI has previously been applied in studies of pregnant women [2,10], and we also evaluated the items to be adequate for this group.

Pain intensity was measured by the response to the following question: "How strong is your worst evening pain before going to bed?" Since PGP has been suggested to increase with activity [9,17], we chose the intensity of the worst evening pain as the most relevant measure for their experienced degree of pain affliction. The response was measured by a 0-100 mm VAS and the end points were "no pain" and "unbearable pain".

Measurements at inclusion in early pregnancy

Potential risk factors for PGP were measured by questionnaire and clinical examination at inclusion in early pregnancy.

Questionnaire data:

Socio-demographical data included age (years), parity (0, 1, ≥2 children), marital status (single, married/cohabitant), education (≤12 years of school attendance, ≤4 years at university, > 4 years at university), use of contraceptive pills last year before pregnancy (yes, no), smoking (yes, no), physical activity before pregnancy (none, < 2, 2 - 4, > 4 hours per week), full time work (yes, no). Pre-pregnancy body mass index (BMI, weight/height^2) was calculated from self-reported height and weight.

The working condition was identified from the question: "How would you describe your work situation?" With four response alternatives: 1) Most of the time seated; 2) I have to walk a lot; 3) I walk and lift objects; 4) Heavy work. PGP was assumed to increase with weight bearing activities like walking and lifting objects [6,9]. Working condition was categorized as mostly seated work (response alternative 1) and heavy work (response alternatives 2-4).

The Hopkins Symptom Check List (HCSL-25) was used to measure distress (self-reported symptoms of anxiety, depression and somatisation) [21]. Twenty-five symptoms were recorded on a scale from 1 (not bothered) to 4 (extremely bothered). The average value was calculated to obtain the HSCL-25 score. We used a cut off value of 1.75 as established for women by Sandanger and co-workers (1998), and the cut-off reflected non-specific distress, rather than a psychiatric diagnosis [22].

Fear avoidance beliefs was measured by the modified Fear Avoidance Beliefs Questionnaire (mFABQ) [23]. This includes four of the items from the part concerning activity in the original Fear Avoidance Beliefs Questionnaire [23,24]. We chose the modified version because it was possible to answer also by individuals without pain. In accordance with the work from Linton and co-workers [23], the following instructions were given in the questionnaire: "Some women are likely to be afflicted by pain in the back and pelvis during pregnancy. For research purposes, we would like to know if you believe that there is a

relationship between such afflictions and activities. Please circle the number on the scale that best corresponds to your belief for each of the following statements". The scale ranged from 0 (total disagreement), to 6 (total agreement), and the total score on mFABQ ranged from 0-24 [23].

Pain locations within the pelvic area (PGP) were determined by a pain drawing filled in by the women before the clinical examination. After the examination, the women were asked to point out the pain sites on their body and, if necessary, the examiner corrected the pain drawing to reflect the areas pointed out. The pain locations in the pelvic area were subsequently coded: no PGP, pain in symphysis only, only posterior pain (uni- or bilateral), combined symphysis pain and unilateral posterior pain, and combined symphysis pain and bilateral posterior pain [3,25]. The two latter categories were collapsed in the analyses (combined symphysis and posterior pain) because of low frequencies.

The number of pain sites was calculated from the questions where the women were asked if they have pain (yes, no) in the neck, shoulder and arms, between the shoulder blades, in the knees. The sum score (0-4) was used in the analyses. Pain located in the area of the lower back and the pelvis was not included in this sum.

Pre-pregnancy history of LBP was identified from the question: "Have you suffered from LBP before you were pregnant (yes, no)?"

Clinical examination:

Beighton score was used as a measure for joint laxity and consists of 9 tests [26,27]: hyperextension of the knees (yes, no), hyperextension (>10°) of the elbows (yes, no), passive apposition of the thumbs to the flexor aspect of the forearm with straight elbow (yes, no), passive hyperextension of the 5th metacarpophalangeal joints $\geq 90^{\circ}$ (yes, no) , forward flexion of the trunk, with knees straight, so that the palms of the hands rest easily on the floor (yes,

no). The angles were measured with a goniometer. A sum score (0-9) was made of the results of all the tests and hypermobility was defined as a sum score of four and above [26].

We used one functional test, the ASLR test, and six pain provocation tests: the P4 test, the distraction test, the compression test, the Patrick Faber test, the palpation test of the symphysis pubis and the long dorsal sacroiliac ligament (LDL). All the tests have been commonly used and have shown moderate to excellent inter-rater reliability [17,18,28,29].

The active straight leg (ASLR) test [18]: The ASLR test was performed with the women in a supine position with straight legs and feet about 20 cm apart. The women lifted each leg separately about 20 cm above the couch. She was asked to score the difficulty on a six-point scale from 0 (not difficult to lift) to 5 (impossible to lift). The scores on both sides were added and the total score ranged from 0-10. In accordance with previous studies, we considered an ASLR sum score of 4 and above as a positive test [30,31].

The Posterior Pelvic Pain Provocation (P4) test [17]: The P4 test was performed with the women in a supine position. The hip and knee on the tested side were flexed to 90°. The examiner stabilized the contra lateral side of the pelvis while a graded force was applied on the flexed knee into the pelvis along the longitudinal axis of femur. Adduction of the hip was avoided. It was recorded whether a familiar pain was felt in the posterior part of the pelvis on the provoked side (yes, no). Both left and right side were tested and scored separately.

Distraction test: The women were examined in supine position. The examiner applied cross-armed pressure to the anterior superior iliac spines (ASIS) directed laterally. This procedure was assumed to stretch the anterior sacroiliac joint ligaments and to give compression in the dorsal part of the sacroiliac joints. The pain response was recorded (yes, no).

Compression test: The woman were examined in side lying position, knees and hips slightly flexed. Pressure was applied vertically into the pelvis when the examiner leaned her

chest against the uppermost iliac crest. The test was assumed to stretch the posterior sacroiliac joint ligaments and compress the anterior part of the sacroiliac joints. The pain response was recorded (yes, no). Both sides were tested and scored separately.

Patrick-Faber test: The women were examined in supine position. The examiner led the ipsilateral leg into flexion, abduction and external rotation so that the heel rested on the opposite kneecap. The examiner stabilized the contralateral side of the pelvis to ensure that the lower back stayed in a neutral position. The ipsilateral knee was lowered against the table and the examiner applied a light overpressure to the subject's knee. It was assumed that both the anterior sacroiliac ligament and the hip joint were stressed [32,33]. The pain response was recorded (yes, no). Both sides were tested and scored separately.

Palpation of the pubic symphysis: The women were examined in supine position. The examiner applied gentle pressure to the pubic symphysis with her hand (flat fingers). If the pressure caused pain that persisted more than 5 seconds after removal of the hand, it was recorded as pain (yes, no).

Palpation of the long dorsal sacroiliac ligament test: The women were examined in side lying position and the examiner palpated the long dorsal sacroiliac ligament at her uppermost side, caudal of the posterior-superior iliac spine. The test was positive if the palpation provoked pain and recorded (yes, no). Both sides were examined and scored separately.

Apart from the P4 test, a sum score was calculated from numbers of positive responses to pain of all the above described pain provocation tests, ranging from 0 (all negative) to 8 (all positive). We decided to use the responses on the P4 test as a single response and not as part of a sum; based on the tests relevance for PGP reported in previous studies [17,34].

Statistics

Descriptive data are given as frequencies, percentages, means and standard deviations (SDs) or medians and ranges. Multiple linear regression analysis was used to study the associations between potential risk factors measured in early pregnancy and DRI or pain intensity in gestation week 30. Associations between the explanatory variables as well as between the explanatory variables and each of the response variables were studied by Pearson correlation coefficients. The explanatory variables showing significant relationship with the response variable were entered into a multiple regression model. The best subsets of explanatory variables were selected through exclusion of the variables with the smallest contribution to the model (the largest p-values). Two adjusted models are presented for each of the response variables, without (model 1) and with (model 2) adjustment for DRI or pain intensity at inclusion in early pregnancy. The residuals were examined to check model assumptions. The statistical analyses were conducted in SPSS version 16.0 and a 5% level of significance was used.

A continuous variable was the main outcome in the power calculations. The level of significance was set to 5% (two-sided) and the power 80%. Assuming a correlation of medium size, 0.3, in the population, a sample size of 85 is required for assessing significance of a correlation coefficient in the sample [35]. In a multiple regression analysis with five independent variables, the required sample size is 91 to detect a medium effect size of 0.15 ($R^2/(1-R^2)$) [35].

Results

Mean gestation week at inclusion in early pregnancy was 14 weeks (SD 3 weeks) for the 268 women participating in this study. They were 18 to 45 years old and 59% were pregnant with their first child. Characteristics of the participants are presented in table 1. A total of 59

women declined participation in the cohort study. There were no difference between participants and non participants with regard to age (mean 31 years and SD 4 years in both groups) and marital status. The non-participants (n=59) were asked about participation in mean gestational week 15 (SD 6 weeks), and 44% were nulliparous. The women excluded from analyses (n=46) due to inclusion later than gestation week 20 were a little older (mean age 32 years, SD 4) and 77% were nulliparous.

Fifty percent of the participants reported pain in the pelvic area in early pregnancy and most of them reported posterior pain only (39%) (table 2). Pain in the symphysis only and combined symphysis and posterior pain were reported by 4% and 7% of the women, respectively. The frequencies of negative responses were high on all the clinical tests (54 – 94%). The sum of pain provocation tests had a median value of 1 (range 0, 6) (table 2). Both DRI and pain intensity increased from early pregnancy to gestation week 30, and showed large variation among the women (table 2).

The correlation coefficients between the potential risk factors and DRI ranged from -0.07 to 0.54 and between potential risk factors and pain intensity ranged from -0.10 to 0.46 (table 3). The correlation coefficients between the potential risk factors ranged from -0.25 to 0.56 and did not suggest collinearity (data not shown). Pain intensity and DRI in gestation week 30 were significantly correlated ($r= 0.63$, $p<0.001$) (table 3).

Pre-pregnancy BMI, smoking, physical activity before pregnancy, full time work and Beighton score for hypermobility were not significantly associated with DRI in gestation week 30 in the bivariate analysis ($0.16\leq p\leq 0.64$). Physical activity before pregnancy, full time work and Beighton score for hypermobility were not significantly associated with pain intensity in gestation week 30 in the bivariate analysis ($0.38\leq p\leq 0.98$). These variables were not entered in to the respective multivariable models. Age, gestation week, pre-pregnancy LBP, and work condition were not significantly associated with the response variables

($0.11 \leq p \leq 0.65$), but were entered into the multivariate models based on associations reported in previous studies [4-9].

In the multivariable model, pain locations, P4 test, sum of pain provocation tests, and HSCL-25 in early pregnancy were significantly associated with DRI in gestation week 30 (Table 4). Age, parity, marital status, education, use of contraceptive pills, the ASLR test, pre-pregnancy history of LBP, work condition, number of pain sites and mFABQ in early pregnancy were not significantly associated with DRI in gestation week 30 in the multivariable analyses ($0.08 \leq p \leq 0.98$). No significant interactions between the explanatory variables were found ($0.21 \leq p_{interaction} \leq 0.97$). When we adjusted for DRI in early pregnancy, R^2 increased from 0.26 (model 1) to 0.37 (model 2) and the sum of pain provocation tests and HSCL-25 were no longer significant ($p=0.26$ and $p=0.49$, respectively) (Table 4). Additional adjustment for gestation week at inclusion did not change the results.

In the multivariable model for pain intensity in gestation week 30 similar results were found (table 5). The same variables were significant except for HSCL-25. Age, parity, marital status, education, use of contraceptive pills, pre-pregnancy BMI, smoking, the ASLR test, pre-pregnancy history of LBP, work condition, number of pain sites, and mFABQ in early pregnancy were not associated with pain intensity in gestation week 30 in the multivariable analysis ($0.07 \leq p \leq 0.80$). No significant interactions between the explanatory variables were found ($0.25 \leq p_{interaction} \leq 0.77$). Adjustment for pain intensity in early pregnancy increased the R^2 from 0.29 (model 1) to 0.33 (model 2) and the sum of pain provocation tests in early pregnancy was no longer significant ($p=0.23$) (table 5). Additional adjustment for gestation week in early pregnancy did not change the results.

The effect estimates of each response variable were relatively large in both models, although the 95% confidence intervals were wide. Yet the effect estimates seemed to be higher for pain intensity compared with DRI. For instance our data shows that pain intensity

in late pregnancy is 40.4 (95% CI: 24.4, 56.6) higher when pain was present in the symphysis only, compared with having no pain in early pregnancy and adjusted for P4 test and sum of pain provocation tests (table 5, model 1).

Discussion

The main results from this study were that pain locations in the pelvis, positive P4 test and sum of pain provocation tests in early pregnancy were significantly associated with disability and pain intensity in late pregnancy. In addition, distress was significantly associated with disability. The functional test ASLR, fear avoidance beliefs and the number of pain sites were not significantly associated with neither disability nor pain intensity.

The risk factors identified in this study differ from those that have been reported before. Strenuous work, pre-pregnancy history of LBP and parity have previously been identified as risk factors for PGP in studies applying bivariate statistics [4-6] and multivariable models [9]. In our bivariate correlation analyses, the first two variables were not significantly associated to neither disability nor pain intensity in gestation week 30, while parity was. None of the variables were significant in the multivariable analyses. This could be due to difference in design or to the use of different levels of statistical methods. One possible explanation for the difference could be that previous studies have often recorded the risk factors retrospectively, late in pregnancy and after the onset of symptoms. Hence, the women's reporting of these factors might be biased by pain [7,8]. The prospective design of the present study ensured that this possible bias was avoided. At the time of inclusion and measurement of the risk factors, none of the women had defined their symptoms as a problem and they were not seeking treatment.

It is also noteworthy that the results of the functional ASLR test measured in early pregnancy, used with a distinction between those with strong affliction and those with none

or lesser affliction, was not significantly associated with disability. This might indicate that severe impairment of motor control and movement of the legs relative to the pelvis was not important for the development of PGP. On the other hand, the response to the P4 test was identified as a risk factor for both pain intensity and disability. Since this test is supposed to elicit a distinct located pain deep in the gluteal area [17], it seems that affliction in the posterior pelvis has an impact on the course. This is, however, partly contradicted by the data from pain locations. Self-reported pain only in the symphysis in early pregnancy had about the same impact on disability and pain intensity in gestation week 30 as did combined symphysis pain and posterior pain. Moreover posterior pain (without symphysis pain) in early pregnancy was not significantly associated with disability and pain intensity in gestation week 30. Since this group was the largest, the lack of effect can hardly be explained by lower test power than the other pain locations. Although the confidence intervals were wide, our data indicate that subclinical afflictions in both anterior and posterior part of the pelvis are of importance for development of pain and disability. Hence, our data suggest that symphysis pain can be an early indicator or precursor for pain development in other areas of the pelvis. Interestingly, the association seems to disappear when pain location and disability are measured simultaneously in late pregnancy [3].

When we included disability or pain intensity assessed in early pregnancy in the multivariable models, some explanatory variables were no longer significant. This means that these variables were not risk factors for the change in disability or pain intensity. However, from a clinical point of view it is more important to identify risk factors for disability and pain intensity late in pregnancy than the change from early pregnancy. This is supported by the data showing an increased DRI already in early pregnancy compared with healthy non-pregnant women [20].

Several of the previously identified risk factors for PGP in pregnancy are similar to those reported for LBP and for other musculoskeletal disorders and are not specific for PGP [36,37]. These comprise socio-demographical factors, previous history of LBP, strenuous work and high level of distress. In contrast, positive response to the P4 test has been shown to be sensitive and specific for PGP [17]. Also the pattern of pain locations within the pelvis is probably specific for PGP, and one might therefore hypothesize that both the P4 test and pain locations are "condition specific" risk factors for PGP.

The response variables used in this study were measured as scale values whereas previous studies have used dichotomous responses for example reporting PGP or not. From the large variation in responses shown when using scales in the present study, one might question to what extent the dichotomous response variables actually reflects important affliction. The dichotomous response variables have resulted in very high prevalence rates for PGP in pregnancy [1,2,10,25]. We have recently found that the variability in DRI was large both for women reporting and not reporting PGP [3]. In order to capture associations to this large range of affliction, the used scales seem to provide additional information than the dichotomous responses.

Previous studies have shown associations between distress, fear avoidance beliefs and activity limitations in patients with LBP [38-42], and also that distress contributed to physical activity and work loss in an acute sample of LBP patients [36]. Our results showed that distress contributed into the model for disability but not for pain intensity. Interestingly the effect of HSCL-25 on disability in gestation week 30 disappeared when we controlled for disability at inclusion. As in the study from Grotle and co-workers of acute LBP [43], fear avoidance beliefs was not identified as a risk factor for either disability or pain intensity.

Over the years, there has been a growing evidence for predictive effect of widespread pain on long term changes in work disability [44]. Furthermore, it has also been reported that

the risk of long-term work disability was lower for persons with localized LBP compared with persons with LBP combined with pain in other bodily areas. The risk for long-term work disability increased with the latter [45,46]. We included number of pain sites (excluding low back and pelvic area) in the multivariable analyses, and found that it did not contribute in any of the models. The lack of effects may be due to the small number of possible pain sites. However, it is also possible that PGP in pregnancy is a specific condition characterized by a rather short course compared with other musculoskeletal pain conditions. Most of the women recover shortly after delivery. One might thus speculate that multiple pain sites are not of importance for development of PGP in pregnancy, but could still be of importance for non-recovery from PGP postpartum.

The present study has several strengths, including the use of a prospective design, continuous response variables and multivariable statistics. Furthermore the implementation of clinical risk factors, use of blinded examiners and the follow-up of all pregnant women in the cohort independent of having PGP or not also strengthen the study.

A limitation that should be considered when interpreting the results is the limited numbers of women in some of the groups. However, even though the confidence intervals are wide, the findings indicate that the risk factors are of importance. On the other hand, lack of significant results should be interpreted with caution.

Another possible weakness could be the representativeness. The women participating in the cohort were about the same age and in the same gestation week as women declining participation. Women who were excluded from analyses due to late inclusion were also about the same age. The average age of women giving birth in Norway have been 30.3 years (2006 – 2007) [47] i.e., almost similar as in our cohort. There were some differences in the percentage of nulliparous women in the non-participant group, the excluded group and the participants (44%, 77% and 59% respectively). The number of nulliparous women in the

cohort was also slightly higher than among Norwegian women (59% vs 42%). We cannot exclude the possibility that another cohort of pregnant women in Norway, would result in somewhat different results with regard to prevalence of pain locations and positive clinical tests. However, the associations between them are expected to be similar.

Implications

Even though most women recover from PGP shortly after delivery, it has been shown that a number of women report pain for longer time periods and that some of them have serious problems [48-50]. Hence it seems important to identify risk factors for development of PGP in pregnancy that could contribute to better management and thereby prevent persistent disability after delivery. Risk factors identified in previous studies, such as parity and strenuous work can hardly be treated or managed for prevention purposes. The identification of the clinical risk factors in the present study therefore opens up new possibilities for management. Prevention and treatment of PGP in pregnancy would have considerable implications for the women, but also for the society in terms of productivity and health costs. However, it remains to be seen whether the risk factors identified in the present study are of clinical value in treatment and prevention of PGP.

Conclusions

In conclusion, we have found that pain locations in the pelvis, bilateral positive P4 test, and sum of pain provocation tests in early pregnancy were significantly associated with disability and pain intensity in gestation week 30. The effect estimates were relatively large. Furthermore distress was significantly associated with disability, but not with pain intensity. Fear avoidance beliefs were not significantly associated with any of the responses. These results thus suggest that a clinical examination including a few tests performed in early

pregnancy may identify women at risk of a more severe PGP late in pregnancy. The identification of clinical risk factors may provide a foundation for development of targeted prevention strategies.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors contributed to the conception and design of the study. HSR, NKV and AMM obtained funding. HSR, NKV and MBV did the data analyses. All authors contributed to the interpretation of the results and critical revision of the manuscript for important intellectual content and approved the final version of the manuscript.

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Figure legends

Figure 1 The study sample

Table 1 Characteristics of the women at inclusion in early pregnancy (n=268)

		Frequency (%)	Mean (SD)
Age (years)			31 (4)
Parity	0	157 (59)	
	1	86 (32)	
	≥2	25 (9)	
Gestation week			14 (3)
Marital status (single)		7 (3)	
Education	≤ 12 years school attendance	46 (17)	
	≤4 years university	113 (42)	
	>4 years university	109 (41)	
Contraceptive pills, year before pregnancy (yes)		103 (38)	
Pre-pregnancy BMI (kg/m^2)			23.3 (3.5)
Smoking (yes)		11 (4)	
Physical activity before pregnancy	None	11 (4)	
	< 2 hours per week	84 (31)	
	2 - 4 hours per week	138 (52)	
	> 4 hours per week	34 (13)	
Full time worker (yes)		228 (85)	
Heavy work (yes)		96 (36)	
mFABQ (0-24)			9.3 (3.8)
HSCL-25 (score ≥1.75)		38 (14)	
Pre-pregnancy history of LBP (yes)		131 (49)	

BMI, Body Mass Index; mFABQ, modified Fear Avoidance Beliefs questionnaire; HSCL-25, Hopkins Symptom Check List; LBP, Low Back Pain

Table 2 Distribution of possible risk factors and outcome variables. (n=268)

		Frequency (%)	Median (range)
Beighton score	Normal (sum<4)	46 (17)	
	Hypermobile (sum≥4)	222 (83)	
Pain locations	No pain	135 (50)	
	Pain in symphysis only	11 (4)	
	Posterior pain only	105 (39)	
	Combined symphysis and posterior pain	17 (7)	
P4 test	Negative	161 (60)	
	Unilateral positive	53 (20)	
	Bilateral positive	54 (20)	
ASLR test	sum<4	240 (90)	
	sum ≥4	28 (10)	
Distraction test	Negative	207 (77)	
	Positive	61 (23)	
Compression test	Negative	251 (94)	
	Unilateral positive	15 (5)	
	Bilateral positive	2 (1)	
Patrick-Faber test	Negative	191 (72)	
	Unilateral positive	39 (14)	
	Bilateral positive	39 (14)	
Palpation of pubic symphysis	Negative	241 (90)	
	Positive	27 (10)	
Palpation of LDL	Negative	145 (54)	
	Unilateral positive	41 (15)	
	Bilateral positive	79 (30)	
Sum of pain provocation tests			1.0 (0,6)
DRI in early pregnancy			13 (0,93)
DRI in gestation week 30			36 (0,81)
Pain intensity in early pregnancy (worst evening pain)			0 (0,82)
Pain intensity in gestation week 30 (worst evening pain)			14 (0,99)

P4 test, Posterior Pelvic Pain Provocation test; ASLR test, Active Straight Leg Raise test; LDL, Long Dorsal Sacroiliac Ligament

Table 3. Correlation between outcome variables and possible predictors measured at inclusion in early pregnancy (n=268)

	DRI gestation week 30	Pain intensity gestation week 30
Pain intensity gestation week 30 (worst evening pain,VAS)	0.63***	
Age (years)	-0.07	-0.10
Parity (0, 1, 2 or more)	0.15*	0.18**
Gestation week in early pregnancy	0.03	-0.04
Civil status (married, cohabitant; yes, no)	0.14*	0.22***
Education (≤12 years of school attendance , ≤4 years university, >4 years university)	0.19**	0.17**
Contraceptive pills, year before pregnancy (yes, no)	-0.13*	-0.04
Pre-pregnancy BMI (kg/m^2)	0.09	0.12*
Smoking (yes, no)	0.06	0.12
Physical activity before pregnancy (none, <2, 2-4, ≥4 hours per week)	-0.05	-0.001
Full time worker (yes, no)	0.05	0.09
Work condition (mostly seated/heavy work)	0.03	0.06
Beighton score for hypermobility	0.01	-0.06
Pain locations (no pain, symphysis pain, posterior pain, combined symphysis and posterior pain)	0.36***	0.44***
P4 test (bilateral negative, uni-/bilateral positive)	0.41***	0.39***
Sum of pain provocation tests (0-8)	0.40***	0.40***
ASLR test (<4, ≥4)	0.18**	0.11
HSCL-25 (<1.75, ≥1.75)	0.26***	0.15*
DRI in early pregnancy (0-100)	0.54***	0.34***
Pain intensity in early pregnancy (worst evening pain, VAS)	0.44***	0.46***
Pre-pregnancy LBP (yes/no)	0.09	0.10
Number of pain sites (0-4)	0.19**	0.14*
mFABQ (0-24)	0.18**	0.10

Pearson's correlation coefficient; ***p≤0.001, **0.001<p≤0.01 *0.01<p≤0.05

VAS, Visual Analogue Scale; BMI, Body Mass Index; P4 test, Posterior Pelvic Pain Provocation test; ASLR test, Active Straight Leg Raise test; HSCL-25, Hopkins Symptom Check List; DRI, Disability Rating Index; LBP, Low Back Pain; mFABQ, modified Fear Avoidance Beliefs Questionnaire

Table 4 Associations between disability in gestation week 30 and risk factors measured in early pregnancy (n=268).

	Crude estimates		Adjusted estimates; model 1		Adjusted estimates; model 2	
	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value
Pain locations						
No pain	Reference	<0.001	Reference	0.007	Reference	0.03
Symphysis pain only	17.7 (6.8, 28.6)		14.0 (3.7, 24.1)		11.8 (2.3, 21.2)	
Posterior pain only	10.7 (6.2, 15.3)		4.8 (-0.2, 9.6)		3.4 (-1.0, 7.8)	
Combined symphysis pain and posterior pain	24.5 (15.6, 33.5)		11.8 (2.6, 21.0)		8.4 (-0.07, 17.0)	
P4 test						
Negative	Reference	<0.001	Reference	<0.001	Reference	<0.002
Unilateral positive	8.0 (2.6, 13.5)		2.2 (-3.4, 7.9)		3.3 (-1.9, 8.6)	
Bilateral positive	19.8 (14.3, 25.2)		12.0 (6.0, 18.0)		10.0 (4.4, 15.6)	
Pain provocation tests (sum)	5.3 (3.9, 6.7)	<0.001	1.7 (0.3, 3.0)	0.02	0.7 (-0.5, 2.0)	0.26
HSCL-25						
<1.75	Reference	<0.001	Reference	0.006	Reference	0.49
≥1.75	14.0 (7.6, 20.3)		8.2 (2.3, 14.0)		2.0 (-3.7, 7.7)	
DRI in early pregnancy	0.6 (0.5, 0.7)	<0.001	-	-	0.5 (0.3, 0.6)	<0.001

[1] Estimated regression coefficients, [2] CI, confidence interval. DRI, Disability Rating Index; P4 test, Posterior Pain Provocation test; HSCL-25, Hopkins Symptom Check List

Table 5 Associations between pain intensity (worst evening pain) gestation week 30 and risk factors measured in early pregnancy (n=268).

	Crude estimates		**Adjusted estimates; model 1**		**Adjusted estimates; model 2**	
	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value
Pain locations						
No pain	Reference	<0.001	Reference	<0.001	Reference	<0.001
Symphysis pain only	44.2 (27.7, 60.6)		40.4 (24.4, 56.5)		35.5 (19.7, 51.1)	
Posterior pain only	23.5 (16.6, 30.3)		15.3 (7.8, 22.8)		11.8 (4.3, 19.2)	
Combined symphysis pain and posterior pain	40.5 (26.9, 54.0)		26.0 (11.6, 40.4)		16.5 (1.8, 31.1)	
P4 test						
Negative	Reference	<0.001	Reference	0.07	Reference	0.01
Unilateral positive	16.5 (7.7, 25.2)		5.8 (-3.1, 14.8)		6.1 (-2.6, 14.7)	
Bilateral positive	28.6 (19.9, 37.3)		15.2 (5.8, 24.6)		13.7 (4.5, 22.8)	
Pain provocation tests (sum)	6.3 (4.5, 8.0)	<0.001	2.3 (0.3, 4.4)	0.03	1.3 (-0.8, 3.3)	0.23
Pain intensity in early pregnancy (worst evening pain)	0.7 (0.5, 0.8)	<0.001	-	-	0.4 (0.2, 0.5)	<0.001

[1] Estimated regression coefficients, [2] CI, confidence intervals. P4, Posterior Pelvic Pain Provocation test

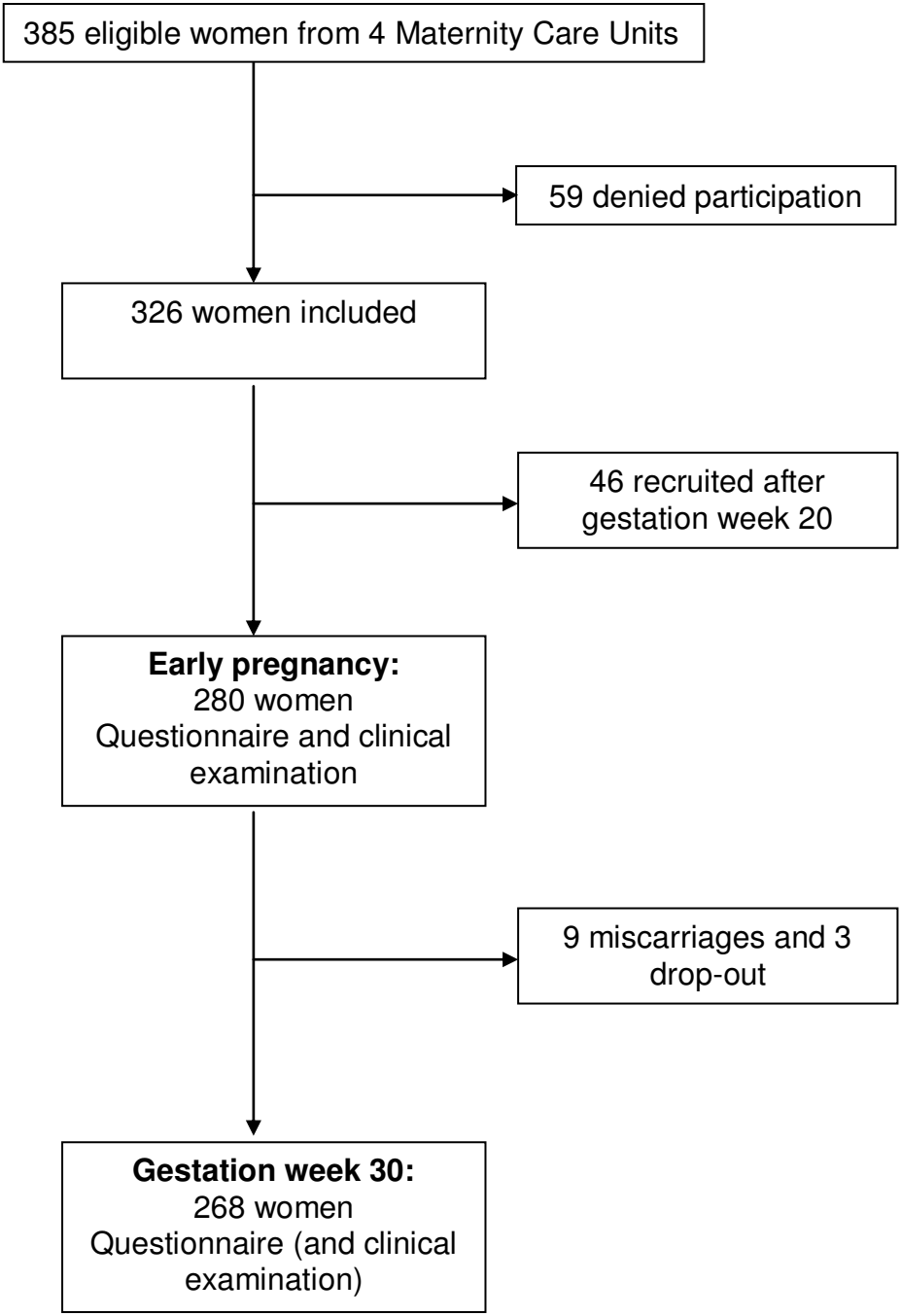
385 eligible women from 4 Maternity Care Units
59 denied participation
326 women included
46 recruited after gestation week 20
Early pregnancy:
280 women
Questionnaire and clinical examination
9 miscarriages and 3 drop-out
Gestation week 30:
268 women
Questionnaire (and clinical examination)

Figure 1

PAPER III

Hilde Stendal Robinson, Anne Marit Mengshoel, Marit B Veierød, Nina K Vøllestad.

Pelvic girdle pain; potential risk factors in pregnancy in relation to disability and pain intensity three months postpartum

Manual Therapy, 2010

TITLE

PELVIC GIRDLE PAIN; POTENTIAL RISK FACTORS IN PREGNANCY IN RELATION TO DISABILITY AND PAIN INTENSITY THREE MONTHS POSTPARTUM

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Pelvic girdle pain; potential risk factors in pregnancy in relation to disability and pain intensity three months postpartum

Abstract

The objective of this prospective cohort study was to examine how results of clinical tests on women with PGP in late pregnancy were associated with disability and pain intensity 12 weeks postpartum controlling for socio-demographical and psychological factors.

Out of the 283 women clinically examined in gestation week 30, 179 were considered afflicted from PGP and constituted the study sample.

Potential risk factors were assessed by questionnaires (at inclusion and in gestation week 30) and clinical examination in gestation week 30. The clinical examination included pain provocation tests for the pelvis as well as the active straight leg raise test. We used pain intensity and disability (disability rating index, DRI) as response variables, derived from questionnaires 12 weeks postpartum.

Using multivariable linear regression analyses, sum of pain provocation tests and pre-pregnancy LBP were significantly associated with DRI 12 weeks postpartum. Furthermore, sum of pain provocation tests and number of pain sites were significantly associated with pain intensity.

In conclusion, we found that when including results of clinical tests as risk factors together with socio-demographical and psychological factors in multivariable regression models, the clinical risk factors are the ones that remain significant. These results are of clinical importance because they seem to have the potential to identify women with a poor prognosis.

Introduction

Pelvic girdle pain (PGP) is a common musculoskeletal disorder during pregnancy and recent studies have reported that prevalence in late pregnancy may be above 50% (Gutke et al., 2006; Mogren, 2006; Robinson et al., 2010a). The prevalence of women with PGP falls substantially during the first 3 months postpartum, reaching about 25% (Ostgaard et al., 1996; Albert et al., 2001; Wu et al., 2004). About ⅕ of those with PGP postpartum are assumed to have serious problems and it would be clinically important to identify these women as early as possible.

Recent studies suggest that pain location could be an important risk factor for sustained PGP postpartum (Albert et al., 2006; Gutke et al., 2008; Vollestad and Stuge, 2009). Gutke et al. reported that low back pain (LBP) in combination with PGP in early pregnancy predicted persistent pain 3 months postpartum (Gutke et al., 2008). Albert et al. reported a slower recovery postpartum among women with combined symphysis and bilateral posterior pelvic pain in pregnancy than among women with fewer pain locations (Albert et al., 2001).

Clinical examinations, including functional tests and pain provocation tests for the pelvic joints, are most often used for diagnostic purposes, and the results have seldom been evaluated as risk factors for sustained PGP postpartum. However, one study reported that women with high numbers of positive pain provocation tests in late pregnancy were more likely to have PGP two years after delivery (Albert et al., 2001). Associations between the bilateral posterior pelvic pain provocation (P4) test in early pregnancy and the development of disability and pain intensity in late pregnancy have been reported (Robinson et al., 2010b). It is of interest to examine whether results of clinical tests may give information about the risk of sustained PGP postpartum.

Previous studies have reported associations between postpartum PGP and pre-pregnancy history of LBP, trauma to the pelvis, multipara, and heavy work loads, but the

evidence is limited (Ostgaard and Andersson, 1992; Breen et al., 1994; Turgut et al., 1998; Albert et al., 2001; To and Wong, 2003; Rost et al., 2006; Vleeming et al., 2008). Studies of LBP have shown that psychosocial factors and emotional distress are important for non-recovery (Cedraschi and Allaz, 2005; Grotle et al., 2005), but such associations have seldom been studied for PGP (Vleeming et al., 2008). However, work dissatisfaction (Gutke et al., 2008) and lack of belief in improvement (Vollestad and Stuge, 2009) have been reported as risk factors for non-recovery from PGP postpartum.

Most previous studies have used women's report of the presence or absence of PGP as response variables, without assessment of the degree of affliction (Albert et al., 2001; Mogren, 2006; Rost et al., 2006). We have previously reported large variations in disability, pain intensity, and consequently the impact on daily life, among women with PGP postpartum and in pregnancy (Stuge et al., 2004; Robinson et al., 2010a). It is therefore of interest to use disability and pain intensity as response measures postpartum.

The main purpose of this study was to examine how clinical assessments in women with PGP in late pregnancy were associated with disability and pain intensity 12 weeks postpartum when we controlled for socio-demographical and psychological factors.

Materials and methods

The present study is a prospective cohort study following pregnant women in Norway from their first contact with the health service (in pregnancy) till 12 weeks postpartum. The potential risk factors were assessed by questionnaires (at inclusion and in gestation week 30) and clinical examination in gestation week 30. The responses were derived from questionnaires 12 weeks postpartum. The examiner was blinded for all questionnaire data. The Regional Committee for Medical Research Ethics and the Norwegian Social Science Data Services gave formal approval of the study.

The cohort

The Norwegian public health service offers all women free health service during pregnancy and most women seek special maternity care units (MCUs) for this purpose. Our cohort comprised 326 pregnant women, recruited consecutively at their first appointment at four MCUs in the Oslo (capital city) area. They were 18 to 41 years old and 59% were pregnant for the first time. During the first 30 weeks of pregnancy nine women reported a miscarriage and three dropped out of the study (figure 1). The women were selected for a new examination in gestation week 30, based on a short questionnaire, including three questions about low back and pelvic pain, distributed by the midwives and answered by the women in gestation week 28. The women had either to be without symptoms of PGP and LBP, or to report pain located in the pelvic area or low back area once a week or more. Furthermore, the pain had to be provoked by sitting, standing or walking. Hence, at gestation week 30, 283 women met and underwent a clinical examination. For the remaining 31 women (9 %) only questionnaire data were collected.

Measurements of response variables, 12 weeks postpartum

Physical disability was assessed by the Disability Rating Index (DRI) (Salen et al., 1994), scoring the ability to perform activities of daily living (dressing without help, outdoor walking, climbing stairs, sitting for a longer period, standing leaning over a sink, carrying a bag, making a bed, running, performing light work, performing heavy work, lifting heavy objects, participating in exercise/sport). These items were scored by visual analogue scales (VAS) ranging from 0 – 100 mm, with end points "ability to perform activity without restriction" and "inability to perform the activity". We calculated DRI as the mean of the twelve scales. DRI has previously been applied in studies of pregnant women (Olsson and Nilsson-Wikmar, 2004; Olsson et al., 2009; Robinson et al., 2010a).

We measured pain intensity by asking: "How intense is your worst PGP before going to bed?" The response was measured by a 100 mm VAS, with end points: "no pain" and "unbearable pain". The intensity of worst evening pain was evaluated and used as the most relevant measure for pain affliction since PGP is said to increase with activity (Ostgaard et al., 1994; Larsen et al., 1999).

Measurements of potential risk factors

Questionnaire data at inclusion:

Socio-demographical data included age (years), parity (0, 1, >1 child), marital status (single, married/cohabitant), education (≤12 years, ≤4 years at university, > 4 years at university), smoking (yes, no), pre-pregnancy physical activity (none, < 2, 2 - 4, > 4 hours per week). Pre-pregnancy body mass index (BMI) was calculated from self-reported height and weight.

Questionnaire data at gestation week 30:

Distress was assessed by the Hopkins Symptom Check List (HSCL) (Rickels et al., 1976). Twenty-five symptoms were ranged on a scale from 1 (not bothered) to 4 (extremely bothered). The average value was calculated to obtain the HSCL-25 score.

Fear avoidance beliefs were measured by the modified Fear Avoidance Beliefs Questionnaire (mFABQ) that can be answered also by individuals without pain (Linton et al., 2000). The mFABQ includes four items from the section concerning physical activity in the original FABQ (Waddell et al., 1993; Linton et al., 2000). In accordance with the work by Linton et al. 2000, the introductory text was: "Some women are likely to be afflicted by pain in the back and pelvis during pregnancy. For research purposes, we would like to know if you believe that there is a relationship between such afflictions and activities." For each item the scale ranged from 0 (total disagreement), to 6 (total agreement), and the sum score from 0 to 24.

We determined pain locations within the pelvic area from pain drawings filled in by the women previous to the clinical examination in gestation week 30. After the examination, the women were asked to point out the pain sites on their body and, if necessary, the examiner corrected the pain drawing to reflect the areas pointed out. The pain locations in the pelvic area were subsequently coded: no PGP, pain in symphysis only, only posterior pain (uni- or bilateral), combined symphysis pain and posterior pain.

We asked the women if they had pain in other bodily areas (yes, no). The areas were: the neck, shoulder and arms, between the shoulder blades, and the knees. The number of pain sites was added (sum score 0-4). Pain located in the area of the lower back and the pelvis was used as separate variables.

Pre-pregnancy history of LBP was identified from the question: “Have you suffered from LBP before pregnancy (yes, no)?”

Clinical examinations in gestation week 30

The active straight leg (ASLR) test (Mens et al., 2001): The ASLR was performed with the women supine, straight legs and feet about 20 cm apart. The women lifted each leg separately about 20 cm above the couch. They were asked to score the difficulty on a six-point scale from 0 (not difficult to lift) to 5 (impossible to lift). The scores on both sides were added and the sum ranged from 0-10.

The Posterior Pelvic Pain Provocation (P4) test (Ostgaard et al., 1994): The P4 test was performed with the women supine. The hip and knee on the tested side were flexed to 90°. The examiner stabilized the contra lateral side of the pelvis while a graded force was applied on the flexed knee into the pelvis along the longitudinal axis of femur. Adduction of the hip was avoided. We recorded whether a familiar pain was felt in the posterior part of the pelvis on the provoked side (yes, no) (Ostgaard et al., 1994). Left and right side were tested and scored separately.

Distraction test (Laslett and Williams, 1994): The women were examined in supine position. The examiner applied cross-armed pressure directed laterally to the anterior superior iliac spines. The pain response was recorded (yes, no).

Compression test (Robinson et al., 2007): The women were examined in side lying position, knees and hips slightly flexed. Pressure was applied vertically into the pelvis when the examiner leaned her chest against the uppermost iliac crest. The pain response was recorded (yes, no). Both sides were tested and scored separately.

Patrick-Faber test (Dreyfuss et al., 1996; Slipman et al., 1998): The women were examined in supine position. The examiner led the ipsilateral leg into flexion, abduction and

external rotation so that the heel rested on the opposite kneecap. The examiner stabilized the contralateral side of the pelvis to ensure that the lower back stayed in a neutral position. The ipsilateral knee was lowered against the table and the examiner applied a light overpressure to the subject's knee. The pain response was recorded (yes, no). Both sides were tested and scored separately.

Palpation of the pubic symphysis (Albert et al., 2000): The women were examined in supine position. The examiner applied gentle pressure to the pubic symphysis with her hand (flat fingers). If the pressure caused pain that persisted more than 5 seconds after removal of the hand, it was recorded as pain (yes, no).

Palpation of the LDL (Vleeming et al., 2002): The women were examined in a side lying position and the examiner palpated the LDL at her uppermost side, caudal to the posterior-superior iliac spine. The test was positive if the palpation provoked pain and recorded (yes, no). Both sides were examined and scored separately.

All tests have been commonly used with moderate to excellent inter-rater reliability reported (Ostgaard et al., 1994; Laslett and Williams, 1994; Mens et al., 2001; Robinson et al., 2007).

Apart from the P4 test, we calculated a sum score of all positive responses from the described pain provocation tests, ranging from 0 (all negative) to 8 (all positive). Based on the P4 test's relevance for PGP reported in previous studies (Ostgaard et al., 1994; Gutke et al., 2009), we decided to use the P4 as a single response and not as part of a sum score. ASLR test was also used as a single response.

The study sample

The women were defined as afflicted in gestation week 30 if : 1) they reported to have PGP (yes, no) and/or had marked in the pelvic area on the pain drawing, and 2) they had a

DRI score above the 25 percentile for the 283 women being examined in gestation week 30 (DRI>22). Both criteria were required, and resulted in 179 women included in the analyses.

Statistical analyses

Descriptive data is given as frequencies and percentages, means and standard deviations (SDs) or medians and ranges or interquartile ranges (IQR). Multiple linear regression analysis was used to study the associations between potential risk factors measured in pregnancy and DRI or pain intensity measured 12 weeks postpartum. Associations between the explanatory variables as well as between the explanatory variables and each of the response variables were studied by Spearman rank correlation coefficients. Explanatory variables significantly associated with the response variable or found important in previous studies were entered into a multiple regression model. The best subsets of explanatory variables were selected through exclusion of the variables with the smallest contribution to the model (the largest p-values). We divided pre-pregnancy BMI, ASLR, and HSCL-25 into two categories (<25, $\geq 25 kg/m^2$) (WHO, 2010), (0, ≥ 1) (Mens et al., 2001) and (<1.75, ≥ 1.75) (Sandanger et al., 1998) respectively, the sum of pain provocation test into four categories (0-1, 2-3, 4-5, and 6-8 positive tests) and the number of pain sites into four categories (0, 1, 2, 3-4). Interaction effects were tested, but real interactions may go undetected since this test lacks power (Kirkwood and Sterne, 2003). The residuals were examined to check model assumptions. Since a large number of the women reported low pain intensity and DRI 12 weeks postpartum, we also repeated the multiple linear regression analyses with pain intensity and DRI ln transformed.

In order to estimate the odds ratios for sustained PGP, we categorized the women as recovered or non-recovered 12 weeks postpartum based on a combination of pain and disability. Women were non-recovered if self-reported PGP and/or markings in the pelvic area

on the pain drawing was present and if the DRI was above 10 (Salen et al., 1994). A logistic regression model was used to study the associations between non-recovery and the same explanatory variables as used in the multiple linear regression analyses. We also used an alternative definition of non-recovery based on the definition described above, but in addition the pain intensity should be above ten. The results from the logistic regression model with the latter response variable were similar; hence these results are not presented.

The statistical analyses were conducted in SPSS version 16.0 and a 5% level of significance was used.

Results

Four percent of the women were single, 5% were smokers and 50% reported a pre-pregnancy history of LBP (table 1). The frequencies of positive responses at gestation week 30 were high on four of the provocation tests (54 – 77%) (table 2). Lower frequencies were observed for the compression test (30%) and the palpation of the pubic symphysis (17%). Sum of pain provocation tests had a median value of 4 (range 0, 8) (table 2).

DRI and pain intensity 12 weeks postpartum had a median value of 5 (IQR 20) and 0 (IQR 12) respectively and were significantly correlated (r_s=0.63, p<0.001). The correlation coefficients between DRI and the potential risk factors ranged from -0.01 to 0.28 and, between pain intensity and the potential risk factors from -0.08 to 0.34 (table 3). The correlation coefficients between the potential risk factors did not suggest collinearity (range -0.28 to 0.36). The only exception from this was a correlation coefficient of 0.75 between the P4 test and sum of pain provocation tests.

Marital status, education, smoking, pre-pregnancy physical activity, and HSCL-25 were not significantly associated with either DRI or pain intensity12 weeks postpartum in the bivariate analysis (0.56≤p≤0.81) (table 3). These variables were not entered in the respective

multivariable models. Age and parity were not significantly associated with any of the response variables ($0.31 \leq p \leq 0.88$) and pre-pregnancy LBP was not associated with pain intensity ($p=0.50$) (table 3). Yet these variables were entered in the multivariable models based on previous studies (Berg et al., 1988; Ostgaard et al., 1991; Kristiansson et al., 1996; Hansen et al., 1999; Mogren and Pohjanen, 2005; Albert et al., 2006). Pain locations were not associated with DRI ($p=0.15$) and the ASLR test was not significantly associated with pain intensity ($p=0.07$). Yet, these variables were entered in the multivariable models based on the hypothesis and previous studies (Albert et al., 2001; Vollestad and Stuge, 2009; Robinson et al., 2010b).

In the multivariable model, pre-pregnancy LBP and sum of pain provocation tests were significantly associated with DRI 12 weeks postpartum (table 4). Pre-pregnancy BMI and the ASLR test were also associated with DRI, though not significantly ($0.05 \leq p \leq 0.07$) Age, parity, pain locations, P4 test and number of pain sites were not significantly associated with DRI ($0.23 \leq p \leq 0.88$) and were not included in the final model. R^2 was 0.18. No significant interactions were found between the explanatory variables ($0.19 \leq p_{interaction} \leq 0.93$).

In the multivariable model, the number of pain sites and the sum of pain provocation tests were significantly associated with pain intensity 12 weeks postpartum (table 5). Pre-pregnancy BMI was associated with pain intensity, though not significantly ($p=0.05$). Age, parity, mFABQ, pain locations, P4 and the ASLR test were not significantly associated with pain intensity ($0.18 \leq p \leq 0.75$) and were not included in the final model. R^2 was 0.16. No significant interactions were found between the explanatory variables ($0.06 \leq p_{interaction} \leq 0.87$).

The analyses were repeated with pain intensity and DRI ln transformed. The same risk factors were identified but the p-values were somewhat changed (table 4 and 5).

Because the P4 test and the sum of pain provocation tests were strongly correlated ($r_s = 0.75$), the analyses were repeated with both variables in the model as well as with each one

separately. The results consistently showed that the P4 test was not significantly associated with either DRI or pain intensity 12 weeks postpartum ($0.14 \leq p \leq 0.80$).

The same explanatory variables as used in the analyses above were also entered into a logistic regression model with non-recovery 12 weeks postpartum as the response variable. Number of pain sites and sum of pain provocation tests were significantly associated with non-recovery (table 6). Pre-pregnancy BMI was also associated with non-recovery, though not significantly ($p=0.05$). The odds increased with increased number of pain sites and OR was 4.4 (95% CI (1.3, 14.6)) for women with 3-4 pain sites as compared to women with no pain sites in the adjusted analyses. Moreover, OR=3.5 (95% CI (1.2, 10.3)) for women with 6-8 positive provocation tests as compared to women with 0-1 positive test.

Discussion

To our knowledge, this is the first study that includes both socio-demographical and psychological factors together with results of clinical tests in multiple regression models, to identify risk factors for disability and pain intensity 12 weeks postpartum. Our results showed that a high number of positive pain provocation tests was a significant risk factor for both disability and pain intensity measured by graded scales 12 weeks postpartum. Furthermore, a high number of pain sites was a significant risk factor for pain intensity. When we used the dichotomous variable for non-recovery as response in a multiple logistic regression analysis, the sum of pain provocation tests and number of pain sites were significant risk factors. Hence the results were quite consistent.

The outcome variables used in the present study differ from what have previously been used. Croft has recently recommended graded scales (Croft, 2009), and in accordance with this we used DRI and pain intensity as measures of affliction. Also when defining the dichotomous response variable for the logistic regression analysis both pain and disability was

included. Hence the outcomes used in both regression models were based on affliction levels and not simply the presence of PGP.

The present study identified two pain related risk factors. Sum of pain provocation tests are supposed directly related to the pelvis and the number of positive tests may thus be assumed to reflect severity of PGP. Hence, it seems that the affliction level of the pelvis itself is important for the degree of recovery postpartum. The other pain related factor, number of pain sites, reflects affliction in other areas of the body. Although only four areas were included in the questionnaire, the number of pain sites in pregnancy was associated with pain intensity and non-recovery postpartum. This finding is in keeping with a prospective study of patients with LBP showing that widespread pain was a risk factor of persistent disabling LBP (Thomas et al., 1999). Furthermore, it has also been shown in a population based study that the number of pain sites is a predictor of work disability (Kamaleri et al., 2009). Hence, it seems that widespread pain is a common risk factor for different groups, including those seeking health care and those less afflicted.

The functional ASLR test was associated with DRI 12 weeks postpartum though not significant. It has been suggested that the ASLR test can assess disease severity in patients with PGP postpartum (Mens et al., 2002), and that there is an association between the ASLR test and mobility in the pelvic joints (Mens et al., 1999), but the evidence for these associations is weak. We have previously shown that the ASLR test was associated with disability, when both factors were measured in gestation week 30 (Robinson et al., 2010a). However, little is known about the relationship between the ASLR test and recovery or improvement in function, although a relationship could be expected.

Interestingly, the P4 test was not associated with either disability or pain intensity 12 weeks postpartum. Even though it has been identified as a risk factor for the development of PGP in pregnancy (Robinson et al., 2010a), the P4 test seems to be of negligible importance

for the prognosis. The P4 and the ASLR test thus seem to differ in their ability to predict the development of PGP in pregnancy and prognosis postpartum. This suggests that the P4 and the ASLR test reflect different aspects of PGP.

Previous studies have shown that pain location was risk factors for sustained PGP after delivery (Albert et al., 2001; Gutke et al., 2008; Vollestad and Stuge, 2009). Our analyses with graded scales could not verify these results. Furthermore, logistic regression analyses, using dichotomous responses gave the same result. Hence the inclusion of clinical tests seems to abolish possible effects of pain locations.

Age, parity, pre-pregnancy BMI and pre-pregnancy LBP have been associated with sustained PGP postpartum in previous studies using bivariate statistics (Ostgaard and Andersson, 1992; Turgut et al., 1998; To and Wong, 2003; Albert et al., 2006) or multivariable models (Breen et al., 1994; Mogren, 2006; Rost et al., 2006). In the present study, pre-pregnancy BMI was associated with both DRI and pain intensity, but not significantly. Pre-pregnancy LBP was identified as a risk factor for disability. Different terminology and definitions, as well as lack of multivariable analyses in previous studies make further comparisons difficult.

Apart from the sum of pain provocation tests, the risk factors for sustained disability and pain intensity postpartum differ from the risk factors identified for development of disability and pain intensity during pregnancy (Robinson et al., 2010b). The difference indicates that the underlying processes for development and prolongation of PGP postpartum are different.

Conclusions

This study shows that results of clinical examinations and tests in late pregnancy are significant risk factors for disability and pain intensity 3 months postpartum, even when

controlling for socio-demographical and psychological factors. The clinical tests used in this study are easy to perform, and the results are of clinical importance because they seem to have the potential to identify women with a poor prognosis. It will be of interest to examine if the clinical factors also represent a risk for pelvic girdle pain and disability when the follow-up period is extended. Furthermore, the clinical risk factors should be used as basis for development of strategies for management of women at risk for sustained PGP postpartum.

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Captions to illustrations

Figure 1 The study sample

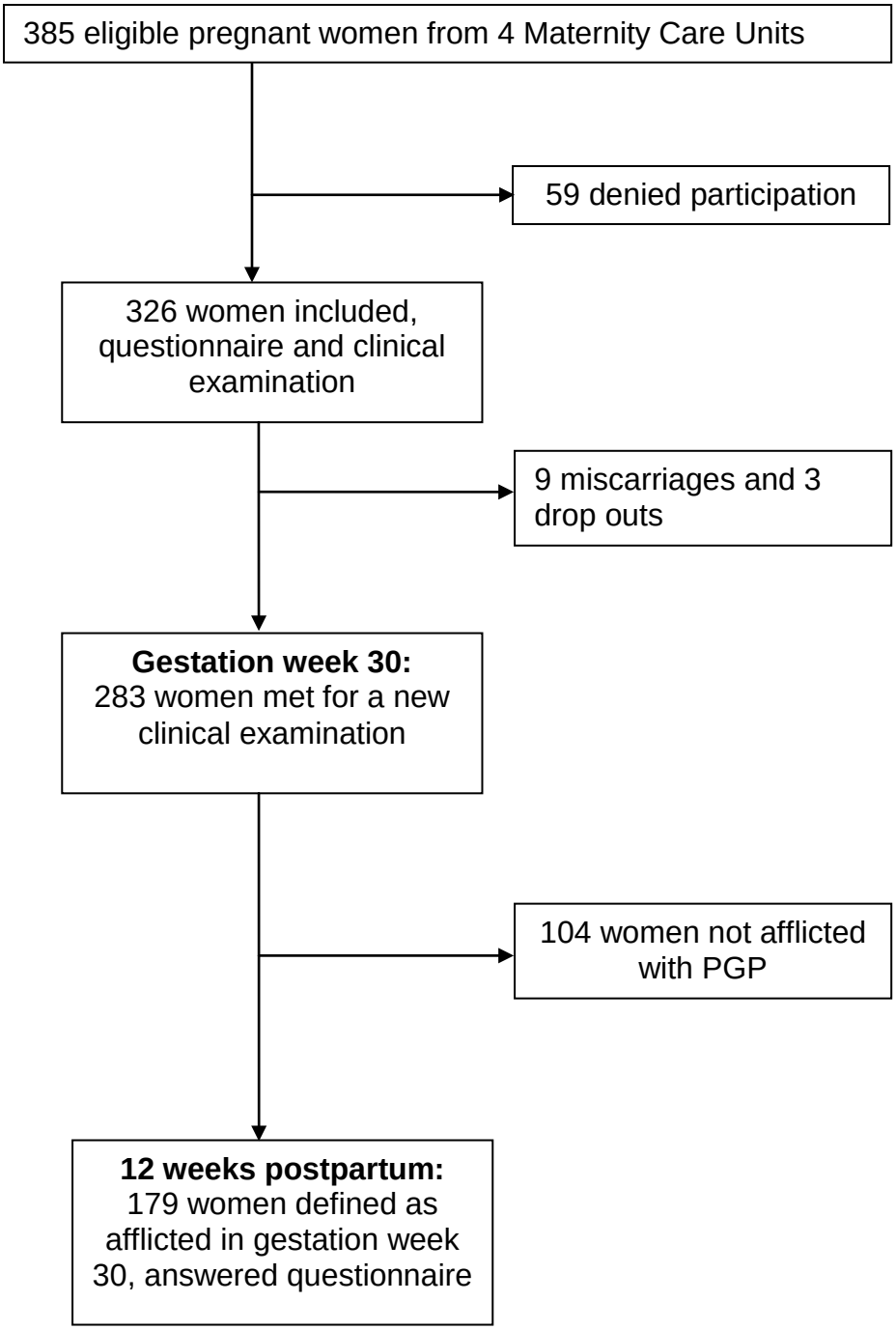
385 eligible pregnant women from 4 Maternity Care Units
59 denied participation
326 women included, questionnaire and clinical examination
9 miscarriages and 3 drop outs
Gestation week 30:
283 women met for a new clinical examination
104 women not afflicted with PGP
12 weeks postpartum:
179 women defined as afflicted in gestation week 30, answered questionnaire

Figure 1

Table 1 Characteristics of the participants (n=179)

		Frequency (%)	Mean (SD)
Age (years)			31 (4)
Parity	0	98 (55)	
	1	64 (36)	
	≥2	17 (9)	
Marital status (single)		7 (4)	
Education	≤ 12 years school attendance	36 (20)	
	≤4 years university	73 (41)	
	>4 years university	70 (39)	
Smoking (yes)		9 (5)	
Pre-pregnancy BMI (kg/m^2)			23.5 (3.7)
Pre-pregnancy physical activity	None	7 (4)	
	< 2 hours per week	56 (31)	
	2 - 4 hours per week	90 (50)	
	> 4 hours per week	25 (14)	
Pre-pregnancy history of LBP (yes)		90 (50)	
mFABQ (0-24)			12.0 (4.2)
HSCL-25 (score ≥1.75)		29 (16)	

BMI, Body Mass Index; LBP, Low Back Pain; mFABQ, modified Fear Avoidance Beliefs questionnaire; HSCL-25, Hopkins Symptom Check List

Table 2 Pain locations and clinical tests in gestation week 30 and DRI and pain intensity 12 weeks postpartum. (n=179)

			Frequency (%)	Median (range)
Pain locations	No pain		3 (2)	
	Pain in symphysis only		12 (7)	
	Posterior pain only		99 (55)	
	Combined symphysis and posterior pain		65 (36)	
Pain provocation tests				
	Distraction test	Negative	83 (46)	
		Positive	96 (54)	
	Compression test	Negative	125 (70)	
		Unilateral positive	33 (18)	
		Bilateral positive	21 (12)	
	Patrick-Faber test	Negative	54 (30)	
		Unilateral positive	51 (29)	
		Bilateral positive	73 (41)	
	Palpation of pubic symphysis	Negative	148 (83)	
		Positive	30 (17)	
	Palpation of LDL	Negative	50 (29)	
		Unilateral positive	44 (25)	
		Bilateral positive	81 (45)	
	Sum of pain provocation tests (0, 8)			4 (0, 8)
	P4 test	Negative	41 (23)	
		Unilateral positive	30 (17)	
		Bilateral positive	108 60)	
Functional test				
	ASLR test (0, 10)			3 (0, 10)
Number of pain sites		0	92 (51)	
		1	44 (25)	
		2	25 (14)	
		3	14 (8)	
		4	4 (2)	

LDL, Long Dorsal Sacroiliac Ligament; P4 test, Posterior Pelvic Pain Provocation test; ASLR test, Active Straight Leg Raise test

Table 3. Correlation between outcome variables (DRI and evening pain 12 weeks after delivery) and risk factors measured in pregnancy (n=179)

	DRI 12 weeks postpartum	Evening pain 12 weeks postpartum
Evening pain 12 weeks postpartum	0.63***	
Age (years)	-0.01	-0.07
Parity (0, 1, ≥2)	-0.07	-0.08
Marital status (married or cohabitant; yes, no)	0.02	-0.12
Education (≤12 years of school attendance , ≤4 years university, >4 years university)	-0.05	-0.09
Smoking (yes, no)	0.13	0.08
Pre-pregnancy BMI (kg/m^2)	0.20*	0.17*
Pre-pregnancy physical activity (none, <2, 2-4, >4 hours per week)	0.02	0.09
Pre-pregnancy LBP (yes, no)	0.20*	0.09
mFABQ (0-24)	0.17*	0.21*
HSCL-25 (<1.75, ≥1.75)	0.10	0.15
Pain locations (no pain, symphysis pain, posterior pain, combined symphysis and posterior pain)	0.11	0.17*
Sum of pain provocation tests (0-8)	0.28**	0.34***
P4 test (bilateral negative, uni-/bilateral positive)	0.20*	0.23**
ASLR test (0,>0)	0.23**	0.14
Number of pain sites (0-4)	0.24**	0.34***

Spearman's correlation coefficient; ***p≤0.001, **0.001<p≤0.01 *0.01<p≤0.05

Table 4 Associations between DRI 12 weeks postpartum and pre-pregnancy BMI, pre-pregnancy LBP, sum pain provocation tests and the ASLR test, the two latter factors were measured in gestation week 30 (n=179). P-values after ln transformation of DRI are also given.

	DRI				**Ln transformed DRI**
	Crude estimates		Adjusted estimates[3]		
	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value	p-value
Pre-pregnancy BMI					
<25 kg/m^2	Reference	0.03	Reference	0.07	0.08
≥25 kg/m^2	5.6 (0.5, 10.6)		4.6 (-0.3, 9.5)		
Pre-pregnancy LBP					
No	Reference	0.04	Reference	0.03	0.01
Yes	5.0 (0.3, 9.8)		5.0 (0.5, 9.5)		
Sum pain provocation tests					
0-1 pos tests	Reference	<0.001	Reference	0.03	0.05
2-3 pos tests	3.4 (-1.7, 10.5)		1.0 (-6.2, 8.3)		
4-5 pos tests	-1.7 (-4.8, 8.1)		-0.4 (-6.9, 6.2)		
6-8 pos tests	12.0 (5.7, 18.3)		7.7 (1.1, 14.3)		
ASLR					
0	Reference	0.005	Reference	0.05	0.03
>0	7.6 (2.3, 12.9)		5.4 (-0.1, 10.9)		

Multiple linear regression analysis
[1] Estimated regression coefficients, [2] CI, confidence interval, DRI, Disability Rating Index.
[3] Adjusted for the other variables in the table; BMI, body mass index; ASLR test, Active Straight Leg Raise test;

Table 5 Associations between pain intensity 12 weeks postpartum and pre-pregnancy BMI, sum of pain provocation tests and number of pain sites (n=179). The two latter factors were measured in gestation week 30. P-values after ln transformation of pain intensity are also given.

	Pain intensity				**Ln transformed pain intensity**
	Crude estimates		Adjusted estimates[3]		
	β[1] (95% CI[2])	p-value	β[1] (95% CI[2])	p-value	p-value
Pre-pregnancy BMI					
<25 kg/m^2	Reference	0.02	Reference	0.05	0.007
≥25 kg/m^2	8.8 (1.5, 15.1)		5.7 (-0.3, 11.8)		
Number of pain sites					
0	Reference	0.03	Reference	0.007	0.001
1	3.9 (-3.5, 11.4)		1.5 (-5.9, 9.0)		
2	9.9 (0.4, 19.3)		8.8 (-0.5, 18.2)		
3-4	21.5 (10.7, 32.3)		18.7 (7.9, 29.6)		
Sum pain provocation tests					
0-1 pos tests	Reference	0.006	Reference	0.04	0.001
2-3 pos tests	5.7 (-4.1, 15.5)		2.3 (-7.4, 11.9)		
4-5 pos tests	5.4 (-3.5, 14.3)		1.3 (-7.4, 10.1)		
6-8 pos tests	15.1 (6.4, 23.8)		11.2 (2.4, 19.8)		

Multiple linear regression analysis
[1] Estimated regression coefficients, [2] CI, confidence interval, DRI, Disability Rating Index.
[3] Adjusted for the other variables in the table; BMI, body mass index

Table 6 Crude and adjusted odds ratios with 95% confidence intervals for non-recovery 12 weeks postpartum due to pre-pregnancy BMI, number of pain sites and sum of pain provocation tests measured in gestation week 30.

		Crude estimates		**Adjusted estimates[3]**	
		β^1 (95% CI^2)	p-value	β^1 (95% CI^2)	p-value
Pre-pregnancy BMI	<25 kg/m^2	1.0		1.0	
	≥25 kg/m^2	2.2 (1.1, 4.4)	0.03	2.1 (1.0, 4.5)	0.05
Number of pain sites	0	1.0		1.0	
	1	2.8 (1.2, 6.2)	0.01	2.3 (1.0, 5.5)	0.05
	2	2.3 (0.8, 6.4)	0.1	2.0 (0.7, 5.7)	0.21
	3-4	5.2 (1.7, 15.9)	0.004	4.4 (1.3, 14.6)	0.02
Sum pain provocation tests	0-1 pos tests	1.0		1.0	
	2-3 pos tests	1.7 (0.5, 5.5)	0.40	1.2 (0.3, 4.0)	0.82
	4-5 pos tests	1.5 (0.5, 4.4)	0.51	1.0 (0.3, 3.3)	0.94
	6-8 pos tests	5.0 (1.8, 14.0)	0.002	3.5 (1.2, 10.3)	0.02

Multiple logistic regression analysis
[1] Estimated regression coefficients, [2] CI, confidence interval, DRI, Disability rating Index
[3] Adjusted for the other variables in the table; BMI, body, mass index

APPENDIX

Information form

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FORESPØRSEL OM DELTAGELSE I FORSKNINGSPROSJEKT:

KVINNERS PLAGER OG FYSISKE FUNKSJON UNDER OG ETTER SVANGERSKAP

Det har tidligere vært gjennomført flere helseundersøkelser i befolkningen, men få har fokusert på kvinner under og etter svangerskap. Seksjon for helsefag ved Universitetet i Oslo i samarbeid med Gamle Oslo helsestasjon og helsestasjonene i Oppegård, er nå i gang med en undersøkelse av kvinners plager og fysiske funksjon under og etter svangerskap. For å få vite noe om dette spør vi deg om du kan tenke deg å delta.
Undersøkelsen er en del av et doktorgradsarbeid ved Universitetet i Oslo.

Praktisk gjennomføring.
Kvinner som skal gå til svangerskapskontroll ved Gamle Oslo helsestasjon og helsestasjonene i Oppegård, blir bedt om å delta i prosjektet. Deltagelse medfører at du må svare på et spørreskjema tre ganger underveis i svangerskapet samt to ganger i løpet av de tre første månedene etter fødsel. Det er derfor nødvendig at du behersker norsk språk både muntlig og skriftlig. Innholdet i disse skjemaene dreier seg om din helse og fysiske funksjon samt om eventuelle smerter eller plager som du opplever underveis i svangerskapet. Utfyllingen av det første spørreskjemaet tar en drøy halv time, de resterende vil ta noe kortere tid. Ved første gangs kontroll på helsestasjonen ønsker vi å ta en blodprøve av deg. Denne blodprøven benyttes til å undersøke innholdet av et hormon (relaxin), som er relatert til svangerskap. Dette hormonet kan være med å påvirke bevegelighet og funksjon hos gravide.

I tillegg ber vi om at en fysioterapeut får lov til å undersøke deg to ganger mens du er gravid samt en gang tre mnd etter fødsel. Dette innebærer at vi tester ut hvor bevegelig du er i leddene dine, om du har noen smerter fra korsrygg og bekken og hvordan du utfører enkle funksjonsprøver. Selve undersøkelsen vil vare ca en halv time hver gang.

Det er frivillig å delta.
Du kan trekke deg fra prosjektet når som helst, uten å oppgi noen grunn, og det får ingen konsekvenser for deg eller for dine videre kontroller på helsestasjonen. Hvis du skulle trekke deg fra prosjektet så vil dine data bli anonymisert, og blodprøven din blir destruert. Prosjektet er meldt til personvernombudet for forskning, Norsk Samfunnsvitenskapelig datatjeneste.

Din sikkerhet.
Alle undersøkelser som benyttes er kjente og godt etablerte og benyttes daglig i undersøkelse og behandling av gravide kvinner. Alle opplysninger vil være konfidensielle og bare brukes så lenge prosjektet pågår. Opplysningene du gir oss oppbevares slik at de ikke kan kobles til deg.

Blodprøven din vil bli avidentifisert og sendt til Hormonlaboratoriet ved Aker Universitetssykehus hvor den analyseres og lagres i en biobank. Denne forskningsbiobanken er godkjent opprettet av Sosial- og helsedirektoratet.

Prosjektet planlegges å være ferdig 31. desember 2009. Etter avslutning vil de innsamlede dataene oppbevares, men uten at deltagerne kan identifiseres. Avhengig av resultatene vi får, kan det hende at vi kontakter deg igjen og spør om du kan tenke deg å svare på noen flere spørsmål. Vi understreker at det er frivillig å være med på en eventuell oppfølging og at du kan takke nei til dette. Hvis du ikke har blitt kontaktet igjen før prosjektet er avsluttet (31.12.09), vil datamaterialet uansett bli anonymisert og blodprøvene destruert.

Prosjektet er tilrådd av Regional komité for medisinsk forskningsetikk (REK).

Dersom du har noen spørsmål er du velkommen til å ta kontakt med meg eller jordmor på helsestasjonen. Jeg kan nås på følgende telefon nummer, 22858421, mobil: 90607081 (med telefonsvarer). Informasjon om prosjektet finnes også på internett: http:/folk.uio.no/hildesr

Med vennlig hilsen

Hilde Stendal Robinson
Prosjektleder, doktorgradsstipendiat

Informert samtykke.

Jeg har mottatt skriftlig og muntlig informasjon, og jeg er villig til å delta i prosjektet ”Kvinners plager og fysiske funksjon under og etter svangerskap”.

Jeg har forstått at deltagelsen er frivillig, og at jeg når som helst kan trekke meg fra undersøkelsen uten å oppgi noen grunn.

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Sted	dato

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Signatur