Pelvic girdle pain and pelvic floor disorders in pregnant Nepalese women

Ranjeeta Shijagurumayum Acharya

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LIST OF PAPERS

Paper I: Shijagurumayum Acharya R, Tveter AT, Grotle M, Khadgi B, Koju R, Eberhard-Gran M, Stuge B. **Cross-cultural adaptation and validation of the Nepali version of the Pelvic Girdle Questionnaire.** J Manipulative Physiol Ther (accepted April 2019).

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THESIS AT A GLANCE

Paper I: Cross-cultural adaptation and validation of the Nepali version of the Pelvic Girdle Questionnaire

Participants and methods: In a methodological study, the Pelvic Girdle Questionnaire (PGQ) was translated and cross-culturally adapted to the Nepali language. Following this, the Nepali PGQ was tested for reliability and validity in 111 pregnant women with pelvic girdle pain (PGP).

Conclusion: The comprehensibility and measurement properties of the Nepali PGQ were acceptable when used among Nepalese pregnant women. The Nepali PGQ showed acceptable internal consistency, test–retest reliability and construct validity. The Nepali PGQ can be used to evaluate PGP in pregnant Nepalese women.

Paper II: Prevalence and severity of low back- and pelvic girdle pain in pregnant Nepalese women

Participants and methods: A total of 1,284 pregnant women were classified into PGP and/or low back pain (LBP) using self-reported questionnaires and body diagrams in a cross-sectional study. The participants completed questionnaires on sociodemographic, pregnancy and workload characteristics.

Conclusion: Pregnancy-related PGP and/or LBP are common in pregnant Nepalese women. One out of three women reported PGP and/or LBP. The women reported high pain intensity, low disability, poor belief in recovery after delivery, and low concern about PGP and/or LBP. Women with a high body mass index, educated husbands and symptoms of pelvic organ prolapse had a higher prevalence of PGP and/or LBP.

Paper III: Pelvic floor muscle training program in pregnant Nepalese women—a feasibility study

Participants and methods: A feasibility study was conducted in 253 pregnant women to address the feasibility of a pelvic floor muscle training (PFMT) program that included attending at least four supervised PFMT follow-up visits and daily PFMT at home. Feasibility was assessed in terms of recruitment capability, sample

characteristics, data collection procedures, outcome measures, and acceptability (attendance for PFMT visits, PFMT adherence and participant experiences) of the program.

Conclusion: PFMT was feasible to perform in pregnant Nepalese women, at least in those living in the district of the study site. Fifty-seven percent of the women attended at least four PFMT visits. Half of the women performed 50–100% of daily PFMT at home. Although most did not have pelvic organ prolapse or urinary incontinence, the women were motivated to perform PFMT and met for PFMT visits.

SUMMARY

Pregnancy-related pelvic girdle pain (PGP), low back pain (LBP) and pelvic floor disorders are important health care issues due to their high prevalence and adverse effects on quality of life. Although pelvic floor disorders such as pelvic organ prolapse and urinary incontinence rank among the most common reproductive health problems in Nepal, knowledge about pregnancy-related PGP and LBP in the country remains sorely limited. Little is also known about implementing for pregnant Nepalese women a prevention and treatment program such as pelvic floor muscle training (PFMT), which has been proven effective in treating pelvic floor disorders in the Western world. The overall aims of this thesis were thus to expand knowledge about pregnancy-related PGP and/or LBP among Nepalese women and to investigate the feasibility of introducing a PFMT program for pelvic floor disorders among pregnant Nepalese women.

The research for the thesis involved two studies. Whereas Study 1 encompassed methodological and cross-sectional studies, Study 2 was a feasibility study. The sample of 1599 participants comprised pregnant women attending antenatal clinics at obstetrics and gynecology departments in two hospitals (i.e. KIST Hospital and Dhulikhel Hospital).

In Study 1, the Pelvic Girdle Questionnaire (PGQ) was translated and cross-culturally adapted into Nepali and its psychometric properties assessed with a sample of 111 pregnant women with PGP. The Nepali PGQ showed acceptable reliability and validity for assessing PGP in pregnant Nepalese women. Next, the Nepali PGQ was applied to assess the prevalence of PGP and/or LBP among pregnant Nepalese women and to explore factors associated with PGP and/or LBP. The cross-sectional study was conducted in two hospitals with a sample of 1,284 pregnant women. The reported prevalence of pregnancy-related PGP and/or LBP was 34%. Women with a high body mass index, educated husbands and symptoms of pelvic organ prolapse showed a higher prevalence of PGP and/or LBP than the others.

In Study 2, a feasibility study was conducted among 253 pregnant women to address aspects of a PFMT program provided to pregnant women receiving antenatal check-ups at Dhulikhel Hospital. The results of the study revealed that

57% of the women attended at least four supervised PFMT sessions. At home, half of the women performed daily PFMT at a rate of 50 to 100%. The findings from the feasibility study could guide the implementation of PFMT as well as future studies on the effectiveness of PFMT in Nepal.

SAMMENDRAG

Svangerskapsrelaterte bekkenleddssmerter, korsryggssmerter og bekkenbunnsplager er viktige helsemessige utfordringer grunnet høy forekomst og negativ effekt på livskvalitet. Mens bekkenbunnsplager, slik som underlivsprolaps og urininkontinens, har vist seg som et av de vanligste kvinnehelseproblemene i Nepal, er det mangel på kunnskap om svangerskapsrelaterte bekkenledds- og/eller korsryggssmerter. Det er vist at bekkenbunnstrening har effekt på forebygging og behandling av bekkenbunnsplager i den vestlige verden, men det er lite kunnskap om implementering av tilsvarende trening i Nepal. Den overordnede hensikten med denne avhandlingen er å øke kunnskapen om svangerskapsrelaterte bekkenledds- og/eller korsryggssmerter, samt å undersøke gjennomførbarheten av et bekkenbunnstreningprogram blant gravide nepalesiske kvinner.

Denne avhandlingen består av to studier. Den første består av to delstudier, en metodisk og en tverrsnittsstudie. Den andre er en feasibility studie. Deltagerne var gravide kvinner som kom til svangerskapskontroll ved obstetrisk og gynekologisk avdeling ved to sykehus i Nepal (KIST Hospital og Dhulikel Hospital). Totalt ble 1599 kvinner inkludert i de to studiene.

I den først studien ble «the Pelvic Girdle Questionnaire» (PGQ) oversatt og kulturelt tilpasset til nepalesisk. Deretter ble måleegenskapene for den nepalesiske versjonen av PGQ testet hos 111 gravide kvinner med bekkenleddssmerter. Resultatene viste at den nepalesiske versjonen hadde akseptabel reliabilitet og validitet. Videre brukte vi denne versjonen av PGQ til å undersøke forekomst av av bekkenledds- og/eller korsryggssmerter i en tverrsnittundersøkelse av 1284 gravide kvinner i Nepal. Det ble også undersøkt hvilke faktorer som var assosiert med svangerskapsrelaterte bekkenledds- og/eller korsryggssmerter hos disse kvinnene. Resultatene viste at forekomsten av svangerskapsrelaterte bekkenledds- og/eller korsryggssmerter var 34%, og kvinner med høy kroppsmasseindeks, utdannede ektemenn og symptomer på

underlivs prolaps hadde en høyere forekomst av svangerskapsrelaterte bekkenledds- og/eller korsryggssmerter.

I den andre studien undersøkte vi hvorvidt det var mulig å gjennomføre bekkenbunnstrening blant 253 gravide kvinner som kom til svangerskapskontroll på Dhulikel Hospital. Resultatene viste at 57% møtte opp på minst fire kontroller med veiledet trening av bekkenbunn. Halvparten av kvinnene gjennomførte også 50-100% av bekkenbunnstreningen hjemme. Funnene fra denne studien vil kunne være nyttige for å implementere bekkenbunnstrening i Nepal. Studien har også lagt grunnlaget for å gjennomføre fremtidige studier på effekt av bekkenbunnstrening i Nepal.

ABBREVIATIONS

BMI	Body mass index
CERT	Consensus on Exercise Reporting Template
CI	Confidence interval
EDS	Edinburgh Depression Scale
EDPS	Edinburgh Postnatal Depression Scale
EMG	Electromyography
ICC	Intraclass correlation coefficient
ICIQ-UI SF	International Consultation of Incontinence Questionnaire–Urinary Incontinence Short Form
IQR	Interquartile range
LBP	Low back pain
NPRS	Numerical Pain Rating Scale
ODI	Oswestry Disability Index
OR	Odds ratio
PFM	Pelvic floor muscle
PFMT	Pelvic floor muscle training
PGP	Pelvic girdle pain
PGQ	Pelvic Girdle Questionnaire
POP	Pelvic organ prolapse
POP-SS	Pelvic Organ Prolapse Symptom Score
RCT	Randomised controlled trial
SD	Standard deviation
SDC	Smallest detectable change
SEM	Standard error of measurement
UI	Urinary incontinence

1 INTRODUCTION

Nepal is a multi-ethnic and multilingual country with a population of around 26.6 million people (1). The country is geographically diverse and divided into three ecological regions: the Terai region (low land plain region), the Hilly region (mountain region that does not generally contain snow) and the Himal region (mountain region containing snow) (1). In 2015, the Nepal government restructured the administrative division of Nepal into provinces (2). Each province is subdivided into districts and each district into municipalities. Nepal has seven provinces, each with 8–16 districts, totalling 77 (Figure 1). Each district has several urban or rural municipalities. There are 293 urban and 460 rural municipalities. The categorisation into urban and rural municipalities is based on criteria including population, infrastructure and revenue (3). Nepal has 126 diverse ethnic and caste groups and about 123 languages, with Nepali being the official language (4). An estimated 55% of the population in Nepal live below the international poverty line, subsisting on less than \$1.25 a day, and 78% subsist on less than \$2 a day (5), making it a low-middle-income country. Around 83% of Nepal's population live in rural areas and depend on farming for their livelihood (1).

Figure 1. Map of Nepal showing provinces and districts.

Women in Nepal live in a conservative and predominantly male-dominated society, where they are generally restricted to childbearing, household maintenance, taking care of the elderly and performing informal unpaid work (6-8). The majority of Nepalese women have limited or no education, resulting in a lack of job opportunities and financial independence (1, 6). Men are considered the head of the family and the decision-maker, which deprives women of making decisions for their own health treatment (6). Women in Nepal also experience potential or actual physical, sexual violence (9).

Since the early 1990s, however, the status of Nepalese women has improved due to better educational status, utilization of health services, economic opportunities and participation in decision-making positions in formal sectors (9). Still, disparity continues to exist between genders, between rural and urban areas, as well as between districts and regions (8, 9). There is an increasing trend of Nepalese people moving to urban areas or high-income countries in search of employment opportunities and better education and lifestyle (10). Nepalese men commonly migrate, and the increase in labour migration has led to a triple role for women, who are involved in reproduction, agricultural production and household work (7, 11). The number of Nepalese women faced with physically strenuous work, little time for rest, and reduced family support, even during pregnancy, is high (12, 13). Nepalese women have a low literacy rate (57.4%) compared to men (75.1%) (4). Moreover, women are disproportionately likely to be in unskilled labour and possess limited property rights (4, 9). Nepalese women, therefore, face a low social and economic status that forms a barrier to quality healthcare (6, 8).

Maternal mortality is an important indicator that reflects the status of women's health (14). Nepal has made remarkable progress in maternal mortality, with a reduction of nearly half from 539 to 281 deaths per 100,000 live births between 1996 and 2006 (15). Gradually, with global progress in maternal mortality rate reduction, the focus has been shifting to maternal morbidity (16). For every woman who dies of pregnancy-related causes, another 20 women (estimated to about 10 million women each year) experience acute or chronic morbidity (17). In Nepal, less than half of women seek care to prevent complications in the postnatal period (1). To increase attendance at antenatal check-ups, Nepal has initiated financial compensation for women attending healthcare check-ups and examinations during

pregnancy and delivery (18). Maternal morbidity has been seen to affect women's physical, mental, social and economic status (19-21). Hence, it is important to address maternal morbidity to improve the health outcomes of women during pregnancy and after delivery.

Pregnancy is supposed to be a happy period of life for women. However, many experience maternal morbidities in relation to pregnancy that have a negative impact on their wellbeing (22). The burden of maternal morbidity rates is estimated to be higher in low-middle-income countries than in high-income countries, especially among the poorest women (22-24). The World Health Organization's Maternal Morbidity Working Group defined maternal morbidity as "any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman's wellbeing and/or functioning" (16). Embedded in this definition is pregnancy-related pelvic girdle pain (PGP) and/or low back pain (LBP), and pelvic floor disorders such as pelvic organ prolapse (POP) and urinary incontinence (UI). These pregnancy-related disorders have been reported worldwide, though with variations in prevalence and symptom severity (25-30). Most studies on pregnancy-related PGP and LBP have been conducted in high-income countries (31-38), with few reported studies in low-middle-income countries (39-42). To our knowledge, the prevalence and severity of pregnancy-related PGP and LBP have never been examined in Nepal.

Before I started my PhD, I had around ten years of experience as a musculoskeletal physiotherapist at an outpatient department at Kathmandu University Dhulikhel Hospital (Dhulikel Hospital) in Nepal, treating patients mainly with musculoskeletal disorders. During these years, I met many women experiencing pain in the lumbar and pelvic area. Most reported LBP; however, after examination and when asked about the site of pain, they pointed to the pelvic area. The clinical presentation of these women made me curious about the prevalence and implications of PGP in Nepalese women.

In contrast to PGP, POP is a pelvic floor disorder that is commonly studied in Nepalese women, and considered a major reproductive health burden. The Nepal government provides free surgery and mobile surgery clinics with the objective of reducing the prevalence of POP (43, 44). This strategy has been criticised because of the absence of adequate follow-up consultations and the

risk of postoperative complications in rural settings (44-47). Pelvic floor muscle training (PFMT) is an evidence-based treatment for pelvic floor disorders, but there is a lack of studies on PFMT for POP and UI in Nepal (6).

As whether it would be feasible to perform PFMT in Nepalese women is uncertain, a feasibility study is recommended prior to a randomised controlled trial (RCT). Both PGP and pelvic floor disorders commonly commence during pregnancy pregnancy (48, 49). Consequently, I wanted to examine PGP and/or LBP and the feasibility of performing PFMT in pregnant Nepalese women.

2 BACKGROUND

2.1 Pregnancy-related pelvic girdle pain

2.1.1 Terminology

Pregnancy has effects on the musculoskeletal system, with the most common musculoskeletal complaints in pregnancy being PGP and/or LBP (49). Many studies on PGP and LBP have described these conditions as one entity, labelled lumbopelvic pain (29, 50-52). Whereas LBP is usually defined as pain between the twelfth rib and the gluteal fold (53), the European guidelines proposed a specific definition for PGP due to the differences in clinical presentation, management and prognosis between PGP and LBP (30). According to the European guidelines, PGP is defined as:

“Pain that generally arises in relation to pregnancy, trauma or reactive arthritis. PGP 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 symphysis. The endurance capacity for standing, walking and sitting is diminished. The diagnosis of PGP can be reached after exclusion of lumbar causes. The pain or functional disturbances in relation to PGP must be reproducible by specific clinical tests”.

The word girdle was added to pelvic pain to differentiate PGP from gynaecological and/or urological disorders (30).

2.1.2 Classification and clinical tests for pelvic girdle pain

To diagnose PGP, pain history should be taken with special attention to pain arising during prolonged standing, walking and/or sitting (30). In addition, to confirm that the pain is in the pelvic area, it is important to indicate the precise area of pain. The patient should either point out the location of pain on her body

or indicate the area on a pain location diagram. Pregnancy-related PGP is typically located in the area of the sacroiliac joints and/or the pubic symphysis (30).

Optimally, the pain should be reproduced by specific clinical tests. Clinical tests are used to confirm a symptom or pain and to provide information about the source of pain and involved structures; however, there is a lack of a gold-standard test for PGP. The European guidelines have recommended several clinical tests to diagnose PGP (30). Commonly used tests are the posterior pelvic pain provocation (P4) test, the active straight leg raise (ASLR) test, palpation of the long dorsal sacroiliac ligament, palpation of the symphysis pubis and the modified Trendelenburg test (54, 55). Among these, the P4 and ASLR tests are of particular interest due to their theoretical and empirical relevance to PGP (56, 57). The P4 and the ASLR tests have been recommended as a reliable and valid diagnostic test for identifying PGP (30, 57-59). The P4 test is a provocation test of the posterior parts of the pelvis that informs about pain location, but not from which anatomical structures the pain emerges. The P4 test has sensitivity of 81% and specificity of 80% (57). The ASLR test is a functional test that examines the ability to transfer weight between the spine and the legs (56). It has been shown to be a reliable test to measure disease severity in pregnancy-related PGP, with sensitivity of 87% and specificity of 94% (59).

2.1.3 Consequences of pelvic girdle pain

PGP is reported to affect daily activities such as walking, lifting, climbing stairs, turning in bed, employment, housework and sexual life, which altogether negatively affects women's quality of life (60, 61). Studies have shown that pregnant women with PGP report a higher impact on physical function than do women with LBP (34, 54). Women who experience PGP present with reduced capacity for functional activities. This affects their sense of identity, independence and ability to care for their children, and they are more likely to have postpartum depressive symptoms compared to women without PGP (61, 62). Hence, PGP greatly affects women functionally, emotionally and socially.

2.1.4 **Epidemiology**

As shown in Table 1, the prevalence of pregnancy-related PGP and LBP during pregnancy varies, with the majority of the studies reporting approximately 50% for unspecified PGP and/or LBP, and 20% for PGP specifically (29, 30). PGP and/or LBP usually appear in gestation week 18, with higher levels of pain intensity between 24 and 36 weeks of gestation (29). Several studies have shown the prevalence of PGP to increase with increasing weeks of gestation (29, 33, 42, 63). One study showed the prevalence of PGP to be 21% at 17 weeks of gestation and 58% at 30 weeks of gestation (63). PGP mostly resolves spontaneously after delivery (63), but 33% of women still report symptoms three months after delivery (64), and in around 5%, PGP may persist for years (29).

The prevalence of PGP and/or LBP (table 1) has been reported in high-income countries (31, 33-38, 50, 51, 54, 63, 65-73) and in low-middle-income countries (39-42, 74), but to our knowledge, not in Nepal. PGP severity and concerns have shown variations across different countries, which might be influenced by societal attitudes, ethnicity and cultural beliefs (75).

Table 1. Summary of studies.

Authors	Country	Design	N	Recruitment	PGP and/or LBP classification/measurements	Parity	Trimester or week of gestation (WoG)	Prevalence
Andersen et al. 2015	Denmark	Nested case-control	5,304	Pregnant women's data from the Danish National Birth Cohort (DNBC)	Self-reported LBP, pain location	Mixed	Mixed trimester	PGP: 19%
Mota et al. 2015	Portugal	Cross-sectional (retrospective?)	105	Postnatal women attending three primary care centres and at the obstetrics service of the hospital	Self-reported LBP	Mixed	Mixed trimester	LBP: 67.6%
Lindgren et al. 2014	Sweden	Prospective cohort	200	Pregnant women attending antenatal clinics	Self-reported back pain, pain drawing, VAS	Mixed	11, 24, 36 WoG	LBP at 11 WoG: 19% LBP at 24 WoG: 47% LBP at 36 WoG: 49% (back pain included cervical, thoracic, lumbar and sacral)
Brown et al. 2013	United Kingdom	Retrospective cohort	580	Mothers with an infant aged zero to six months through mother and baby groups and online forums	Self-reported pain for different body regions, pain location, VAS	Mixed	Mixed trimester	First trimester: LBP 12.4%, PGP: 12% Second trimester: LBP: 21.5%, PGP: 34.5% Third trimester: LBP: 68.2%, PGP: 79.9%
Gjestland et al. 2013	Norway	Cross-sectional	2,753	Women recruited at routine foetal ultrasound	Self-reported LBP, PGP	Mixed	32 WoG	LBP: 51.2% PGP: 51.7%
Bjelland et al. 2013	Norway	Prospective cohort	73,418	Pregnant women scheduled to give birth at 50 hospitals	Self-reported PGP, pain location	Mixed	Third trimester	PGP at 17 WoG: 21.1% PGP at 30 WoG: 58%
Stomp-van et al. 2012	Netherlands	Prospective cohort	548	Dutch pregnant employees	Pain location, pain NRS	Mixed	30 WoG	PGP: 73%
Mens et al. 2012	Netherlands	Cross-sectional	182	All pregnant women visiting the participating practices	Self-reported LBP or pelvic area, pain location, NRS, disability	Mixed	20, 30 WoG	LPP: 60.4%
Malmqvist et al. 2012	Norway	Retrospective cohort	569	All term singleton pregnancies of at least 36 weeks, recruited within hours after delivery	Self-reported LBP and PP, pain drawings, NRS, ODI	Mixed	≥36 WoG	LPP: 57.4%
Al-Sayegh et al. 2012	Kuwait	Cross-sectional	280	Pregnant women visiting women's health clinics, maternity hospital and public venues	Self-reported LPP, pain location, VAS, ODI	Mixed	Mixed trimester	LPP: 91%

LBP: low back pain; PGP: pelvic girdle pain; LPP: lumbopelvic pain; PP: pelvic pain; ODI: Oswestry Disability Index; NRS: numeric rating scale; VAS: visual analogue scale; RMD: Rolland–Morris Disability

Table 1 continued.

Authors	Country	Design	n	Recruitment	PGP and/or LBP classification/measurements	Parity	Trimester or week of gestation (WoG)	Prevalence
Kovacs et al. 2012	Spain	Cross-sectional	1,158	Pregnant women attending a primary care or hospital centre	Self-reported LBP and PGP, pain drawing, VAS	Mixed	>28 WoG	LBP: 71.3% PGP: 64.7%
Pierce et al. 2012	Australia	Cross-sectional	96	Women with a singleton pregnancy attending their antenatal appointment	Pain diagram, pain VAS, ODI	Mixed	Third trimester	LPP: 71%
Charpentier et al. 2012	Canada	Cross-sectional	80	Pregnant Beninese and Canadian women attending antenatal clinics	Self-reported LBP, ODI	Mixed	25 WoG	Back pain: Beninese women: 83% Canadian women: 58%
Chang et al. 2011	Taiwan	Cross-sectional	187	Pregnant women recruited through obstetric gynae outpatient clinics	Self-reported LPP, Brief Pain Inventory	Mixed	35, 41 WoG	LPP: 74.9%
Gutke et al. 2006	Sweden	Prospective cohort	313	Pregnant women attending antenatal clinics	Pain drawing, VAS, ODI, physical examination	Mixed	12 to 18 WoG	PGP: 54%, LBP: 17%, PGP and LBP: 29%
Robinson 2010	Norway	Prospective cohort	268	Pregnant women attending maternity care	Pain drawing, pain location, VAS, DRI	Mixed	30 WoG	PGP: 52%
Ansari 2010	Iran	Cross-sectional (retrospective)	103	Pregnant women admitted in a maternity ward	Pain location	Mixed	Mixed trimester	LBP: 57.3%
Mohseni 2009	Iran	Cross-sectional	1,062	Pregnant women attending health centres	VAS, ODI	Mixed	Mixed trimester	LBP: 55%
Ramachandra et al. 2015	India	Cross-sectional	261	Pregnant women who attended antenatal physiotherapy classes	Self-reported musculoskeletal pain, pain location, clinical tests	Primiparous	Mixed trimester	First trimester: LBP: 3.3%; PGP: 3.3% 2nd trimester: LBP: 42%; PGP: 37% 3rd trimester: LBP: 33.7%; PGP: 32.5% LPP: 44%
Olsson et al. 2009	Sweden	Prospective cohort	324	Pregnant women attending antenatal clinics	Pain location, VAS, DRI, NHP, FABQ, PCS	Mixed	19 WoG	LPP: 49.5% (PGP: 28%, LBP: 13.2%)
Mousavi et al. 2007	Iran	Cross-sectional	325	Pregnant women who attended two large women's hospitals	Self-reported LBP, clinical tests, pain location, VAS	Mixed	12, 36 WoG	Pelvic instability: 12 WoG: 0.5% 36 WoG: 7.3%
Van de Pol et al. 2007	Netherlands	Prospective cohort	412	Pregnant women attending antenatal clinics	Self-reported PGP, pain location, Pregnancy Mobility Index	Nulliparous	12, 36 WoG	LBP: 2/3 of the women
Skaggs et al. 2007	USA	Cross-sectional	599	Pregnant women attending multidisciplinary clinic at a hospital	Self-reported back pain, pain location, NRS	Mixed	Mixed trimester	PGP: 46%
Robinson et al. 2006	Norway	Retrospective cohort	1,817	Pregnant women identified through the Norwegian Central Person Registry	Self-reported PGP, pain location	Mixed	Mixed trimester	

LBP: low back pain; PGP: pelvic girdle pain; LPP: lumbopelvic pain; PP: pelvic pain; ODI: Oswestry Disability Index; NRS: numeric rating scale; VAS: visual analogue scale; NRS: numeric rating scale; NHP: Nottingham health profile ; FABQ: Fear avoidance beliefs questionnaire ; PCS: Pain catastrophizing scale ; DRI: Disability rating index

2.1.5 Aetiology

The causes of pregnancy-related PGP and/or LBP are not well understood, although mechanical (76, 77), traumatic (78), degenerative (79), hormonal (80) and metabolic (81) factors have all been proposed. The most common hypothesis for the development of PGP is a combination of hormonal and biomechanical factors (30). The pelvis (Figure 2) is a bony platform that transmits load from the trunk to the legs. The muscles, fascia and ligaments provide support to the pelvic region (82, 83). During pregnancy the release of the hormone relaxin is increased (84). A systematic review that included five case-control studies and one prospective cohort study investigated the association between relaxin levels and PGP during pregnancy, and found only a weak association (85). Stureson et al. (86) found no differences in mobility between symptomatic and asymptomatic sacroiliac joints, using precise roentgen stereophotogrammetric analysis, and discussed that increased mobility could not be the cause of the pain. Similarly, Kibsgaard et al. (87, 88) found no differences in sacroiliac joint movement between symptomatic and asymptomatic sacroiliac joints. Damen et al. (89) used Doppler imaging of vibrations to examine sacroiliac joint mobility and showed that asymmetric mobility in the sacroiliac joint was associated with PGP. A systematic review that examined the relationship between increased mobility of the pelvic joints and PGP and/or LBP concluded that the motion of the pelvic joints is larger in patients with PGP and/or LBP during the last months of pregnancy and the first weeks after delivery than in healthy controls (90). Another systematic review on the association between altered kinematic, kinetic and motor control of the pelvis and PGP during pregnancy reported a moderate association between PGP and altered mechanical and motor control of the pelvis (91). Hence, the aetiology of PGP is still not well understood.

Figure 2. Illustration of the pelvis with symphysis pubis and sacroiliac joints (© Anne Therese Tveter).

2.1.6 Risk factors for pelvic girdle pain

Several possible risk factors for developing PGP during pregnancy have been reported in previous studies (29, 30, 92). In a review of 34 studies, Wu et al. (29) identified strenuous work and previous history of PGP or LBP as strong predictors for pregnancy-related PGP and/or LBP. Physically strenuous work has been associated with an almost 50% increased risk of PGP in pregnancy (92). According to the European guidelines, the risk factors for the development of PGP are a history of LBP prior to pregnancy and previous trauma to the pelvis (30). More recently, one study found that pain location in the pelvis, positive P4 test, and positive ASLR test were significantly associated with disability and pain intensity late in pregnancy (54). A large cohort study showed that PGP was more common in third-time mothers (21%) compared to second-time (18%) and first-time mothers (11%), indicating that parity is associated with PGP (93). Another large cohort study showed that the risk of pregnancy-related PGP increased with increasing pre-pregnancy body mass index (BMI) (94). The risk of non-recovery from PGP in pregnancy might increase with pain severity in pregnancy week 30

(63). However, most studies on risk factors are cross-sectional and not methodologically sufficient to provide significant information on risk factors for the development of PGP.

2.1.7 Treatment for pregnancy-related pelvic girdle pain and/or low back pain

Even though pregnancy-related PGP is common worldwide, treatment for PGP seems to be ignored by healthcare professionals (36, 95). Women with PGP have described a lack of attention to, knowledge about and understanding of PGP from healthcare providers, and also report an unmet need for treatment (95). Various treatment options, such as exercise, pelvic belts, transcutaneous electrical nerve stimulation, yoga and acupuncture exist for pregnancy-related PGP and/or LBP (96-98). A systematic review examining 22 RCTs found that exercise therapy is effective in the treatment of PGP and/or LBP during pregnancy (98). Another systematic review of 56 studies on the effect of physiotherapeutic interventions on pregnancy-related lumbopelvic pain found a positive effect of acupuncture and pelvic belts and a weak effect of specific exercises (97). A Cochrane review that included 34 RCTs assessing the effects of interventions to prevent and treat pregnancy-related PGP and/or LBP found moderate to low quality evidence for exercise in improving functional disability (96). Additionally, acupuncture and multimodal intervention (manual therapy, exercise and education) were also found to improve pregnancy-related PGP. Few effect studies on the treatment for PGP and/or LBP were found from low-middle-income countries (99-102) and none from Nepal. Before considering a physiotherapeutic effect study in Nepal, increased knowledge about the prevalence and severity of pregnancy-related PGP and/or LBP in Nepalese women is needed.

2.2 Pelvic floor disorders

2.2.1 Pelvic floor muscle anatomy and function

The pelvic floor consists of pelvic floor muscles (PFMs), connective tissue, ligaments, fascia and skeletal structure that forms a hammock across the pelvis (103, 104). As shown in Figure 3, the PFMs are composed of superficial and deep layers. The superficial layer is part of the urogenital diaphragm that consists of the ischiocavernosus, bulbospongiosus and transverse perineal muscles. The deep layer is formed by the muscles of the levator ani, which is subdivided into the pubococcygeus, puborectalis and iliococcygeus muscles (105-107). The subdivisions of the levator ani muscle have different muscle fibre paths, origins and insertions (105, 107). The iliococcygeus muscle forms the posterior part of the levator ani muscle (105, 107). The pubococcygeus (puboperineal, pubovaginal and puboanal muscles) and the puborectalis form the anterior and medial part of the levator ani that forms a U-shaped muscle sling. The space between the inferior pubic rami and the puborectalis component of the levator ani muscle, through which the urethra, vagina and rectum pass, is known as the levator hiatus (108).

Figure 3. Illustration of the pelvic floor muscles (© Anne Therese Tveter).

The PFMs provide support to the pelvic organs (bladder, urethra, vagina, uterus and bowel) against gravity and abdominal pressure (103, 105). Together with the supportive ligaments and fascia, the PFMs contribute to maintaining continence, voiding, defecation, intercourse and vaginal delivery (103, 109-112). The PFMs function by contraction and relaxation. During the resting phase, the pelvic floor muscles and the supporting ligaments support the pelvic organs (105, 113). The PFMs also involuntarily contract to keep the pelvic openings closed and elevate the pelvic floor in a ventrocephalic direction (103, 105). Additionally, the PFMs react automatically to any increase in abdominal pressure (e.g. coughing, laughing, sneezing) by contracting (103, 113). In a voluntary PFM contraction, urethral pressure increases and stabilises the urethra and the bladder neck (103, 105, 114). A voluntary PFM contraction is an inward lift and squeeze around the urethra, vagina and rectum (115, 116). The muscle primarily responsible for the squeeze and lift function of the PFMs is the levator ani (105, 107). When the PFMs relax, the perineum and pelvic organs return to their anatomical resting positions (105, 113). Abnormal function of the pelvic floor is often described as mechanical and neurological disruption of the normal functional anatomy of the pelvic floor structures (109, 117). Pelvic floor disorders are a broad category of disorders that affect the structure and/or function of organs in the female pelvis (103, 109, 117). The most prevalent pelvic floor disorders are POP and UI (25-28).

2.2.2 Pelvic organ prolapse

Epidemiology

The International Continence Society defines POP as the “descent of one or more of the anterior vaginal wall, the posterior vaginal wall, the uterus (cervix), or the apex of the vagina from the normal anatomical position” (118). Anatomical POP is assessed by the POP-Quantification tool, which describes anatomical findings without consideration of symptoms and classify POP into five stages (119).

Symptomatic POP is commonly reported by self-reported questionnaires, where the symptom that is strongly associated with POP is “feeling a bulge into or out of

the vagina” (119). Symptomatic POP greatly affects the quality of life of women (120). The overall prevalence of POP ranges from 3% to 93%, depending on the definition used (26, 121, 122). Based on POP-Quantification, the prevalence is reported to be between 41% and 51% and symptomatic POP ranges from 3% to 10% in high-income countries (26, 119, 121, 122). The reported mean prevalence of symptomatic POP in low-middle-income countries is 19.7% (range 3.4%–56.4%) (28). In Nepal, symptomatic POP has been reported to be between 10% and 36% (12, 123-125).

Aetiology

The aetiology of POP is considered to be multifactorial (126). One major factor is alteration in the supportive role of the pelvic diaphragm, caused by tearing and stretching of the endopelvic ligaments and fascia, PFMs and nerves of the pelvic floor (103, 111, 127). During vaginal birth, all women sustain stretching of their pelvic floor, but only some experience pelvic floor injuries (105, 109). The levator ani has been found to have major defects in women after delivery (117).

Weakening of the levator ani may cause enlargement of the levator hiatus and descent of the central portion of the pelvic diaphragm (103, 105, 108). When this occurs, the pelvic diaphragm loses its support to the pelvic organs, which place tension on the endopelvic fascia. Excessive tension on the endopelvic fascia and increased intra-abdominal pressure due to downward thrusts on the pelvic organs may cause breaks, separations and attenuations within the endopelvic fascia. Additionally, direct and indirect damage to the vaginal wall will increase the possibility for development of POP (103, 105, 111).

Risk factors

A systematic review conducted by Vergdelt et al. (48) included ten studies that investigated risk factors for POP. The authors concluded that the major risk factors for POP were parity, vaginal delivery, age and BMI. However, this systematic review only included studies that were conducted in high-income Western countries. The reported risk factors for POP in low-middle-income countries are damage to the pelvic support mechanism during childbirth, parity,

age and vaginal delivery (28). Reported risk factors for POP in Nepalese women are strenuous physical work during pregnancy and immediately after delivery, lack of skilled birth attendants, malnutrition, high parity and early marriage (128, 129). The consequences of the strenuous burden of work for women in Nepal have been directly linked to the risk factors for POP and UI (128, 129).

2.2.3 Urinary incontinence

Epidemiology

UI is defined as an involuntary loss of urine (118). A systematic review by Hunskaar et al. (25) including 36 epidemiological studies from 17 countries showed a prevalence of UI from 5% to 69%, with the majority of the studies in the range of 25% to 45%. Another review by Walker et al. (28) included 21 studies from low-middle-income countries and showed the mean prevalence of UI to be 28.7% (range 5.2%–70.8%). A systematic review of 17 epidemiological studies conducted in Europe reported the prevalence of UI to be from 14.1% to 68.8% (130). The authors further reported that the reason for the wide variability in the estimates of prevalence might be due to the variation in methods used to collect data and how UI was diagnosed (130).

Studies of the prevalence of UI during pregnancy have shown to range between 18% and 67% (131-134). The prevalence of UI has been reported to be high in parous women (132, 133) and with increasing weeks of gestation (134). In a study by Sharma et al. (135), the prevalence of UI was reported to be 24.1% in first trimester, 23.6% in second trimester and 27.9% in third trimester. A large Norwegian cohort study reported that the prevalence of UI increased from 15% before pregnancy to 48% at gestational week 30 for nulliparous women, and from 35% before pregnancy to 67% at gestational week 30 for parous women (133). A literature search prior to the start of the studies conducted for this thesis revealed only one study reporting the prevalence of UI in Nepalese women (136). The study was conducted in a tertiary hospital located in the Eastern part of Nepal. Among the 630 women screened, 50.6% reported UI. The majority of the

women recruited were between 40 and 49 years old and were mostly multiparous.

Aetiology

The main aetiological factors in the development of UI are pregnancy and childbirth (25). During pregnancy, the woman's body undergoes hormonal, anatomical and physiological changes to permit the appropriate development of the foetus and to prepare the body for childbirth. The hormonal changes alter the viscoelastic properties of connective tissue, peripheral nerves and muscular structure of the pelvic floor, which may lead to UI (132). The increased bladder pressure due to the growing uterus and weight of the foetus may lead to reduced PFM strength as well as their supportive and sphincteric function leading to urethral sphincter incompetence (137).

Risk factors

A systematic review conducted in a European population found that maternal age, increased BMI, and pre-existent UI were the most common risk factors for UI during pregnancy (130). A large population-based survey conducted in Norway showed that UI was associated with age and BMI (138). Another cross-sectional study concluded that the major risk factors for UI are age, pregnancy, previous vaginal delivery, postpartum incontinence and hysterectomy (139). Walker et al. (28) reported that in low-middle-income countries, the risk factors for developing UI were increasing parity, advancing age and vaginal delivery.

2.2.4 Treatment for pelvic organ prolapse and urinary incontinence

Various treatment options are available for POP and UI (140-144). Treatments for POP include surgery, pessaries and PFMT (143, 144). Treatments for UI include PFMT, behavioural techniques, medication, surgery, nerve stimulation, and containment products such as pads and catheters (140-142). Surgery seems to

have a high cure rate for POP and UI (142, 143), but has been contradicted as it is expensive and has a high recurrence rate (145, 146). In the United States, more than 300,000 surgical procedures occur for POP per year (18 per 10,000 women), with 20.8% reporting surgical complications (147). In Nepal, surgery is also one of the common treatments for POP (43, 44, 47). Governmental and non-governmental organizations provide surgery for women with POP through mobile surgical camps and free surgical services at designated hospitals (44). However, surgical treatment has been questioned due to the likelihood of POP recurrence, high costs and limited access to surgery for POP (6, 145). Studies from Nepal have reported postoperative complications (infection, wound dehiscence and vault prolapse) and loss to follow-up in women undergoing POP surgery in temporary health camps (43, 47). Moreover, it has been reported that women may require further revision surgeries later, which might be difficult to provide due to a lack of follow-up by the women (43, 45, 46). Hence, surgery does not seem to be an optimal treatment for women with POP or UI in Nepal.

Pessaries are an alternative non-surgical treatment for POP in Nepal. A general disadvantage of using ring pessaries is the possibility of infection due to a lack of hygienic care (148). Hence, pessaries are not recommended for patients who are non-compliant or lack follow-up (148). Women who use pessaries need regular follow-up visits for the examination of the pessary, including checking for discoloration, cracking and deformation to prevent infection and other complications. A study from Nepal where ring pessaries were used in women with POP reported complications such as pessary extrusion, pain, discharge and UI (45). A Cochrane review also highlighted the lack of robust evidence regarding the effectiveness of vaginal pessaries (149).

PFMT has been shown to prevent the progression of POP and UI, and reduce associated symptoms, with no adverse effects (141, 144, 150, 151). A Cochrane review by Hagen et al. (144) on the prevention or treatment of POP showed that PFMT increases the chance of improvement of POP by 17% compared to no PFMT. Another Cochrane review by Boyle et al. (141) on the prevention of UI showed that women who attended antenatal PFMT were 30% less likely to have

UI six months after delivery, compared to standard care or no treatment (risk ratio 0.71, 95% CI 0.54 to 0.95). Hay-Smith et al. (152) also found that PFMT during pregnancy reduced the likelihood of UI in late pregnancy by around 56% when compared to standard care or no treatment (risk ratio 0.44, 95% CI: 0.30 to 0.65).

Pelvic floor muscle training

PFMT and its importance were introduced by Kegel in 1948, with a focus on treating UI (116, 153). Today, PFMT is recommended as the first-line conservative treatment for women with UI (141, 150, 152) and POP (144). The main rationale for why PFMT works is first that women learn how to consciously pre-contract the PFMs before and during situations that cause increased abdominal pressure (such as coughing), and second that increased PFM strength and hypertrophy occur, building up long-lasting muscle volume to provide structural support (154). Like any other skeletal muscles, the PFMs respond to strength training by improved neuromuscular function, increase in muscular cross-sectional area, increase in number and firing rate of motor units, and improved muscle tone (154-156). Additionally, similar to general strength training, overload and specificity training are considered the most effective strength muscle training programs for PFMs (155, 157, 158). The protocol for PFMT follows recommendations for general strength training of skeletal muscle, which is eight to 12 maximal contractions, three to four sets, three to four times per week (150, 159). The same protocol has been used in various studies and has been shown to significantly increase PFM strength (150, 151, 160). Specific training for PFMs requires correct PFM contraction that should be performed in a correct manner: inward lift of PFMs and squeezing around the urethra, vagina and rectum, without co-contraction of other muscles (161, 162). However, studies have reported that 30% to 40% of women was not able to perform PFM contractions correctly (163, 164).

At the start of the thesis research, a literature search was performed regarding the effect of PFMT in Nepalese women. We could not find any published studies examining the effect of PFMT in pregnant Nepalese women, despite the

recommendation of PFMT as prevention and treatment for women with POP in Nepal (6). Hence, with the strong international evidence for PFMT, we planned to examine the feasibility of performing PFMT in pregnant Nepalese women.

3 AIMS OF THE THESIS

The overall aims of this thesis were to increase the knowledge about pregnancy-related PGP and/or LBP in Nepalese women, and further to acquire knowledge about the feasibility of performing a PFMT program for pelvic floor disorders in pregnant Nepalese women.

The specific aims were:

- To translate and cross-culturally adapt the Pelvic Girdle Questionnaire (PGQ) into Nepali and to examine the internal consistency, test–retest reliability and construct validity of the Nepali PGQ (paper I).
- To assess the prevalence and severity of PGP and/or LBP in pregnant Nepalese women, including functional limitations, pain intensity, belief in recovery, and concern about PGP and/or LBP (paper II).
- To analyse the associations between sociodemographic and condition-related variables and PGP and/or LBP (paper II).
- To evaluate the feasibility of performing a PFMT program in pregnant Nepalese women in terms of recruitment capability, sample characteristics, data collection procedures, outcome measures and acceptability of the program (paper III).

4 MATERIALS AND METHODS

4.1 Designs

The present thesis involved two separate studies that resulted in three papers. In Study 1, we assessed the prevalence and severity of PGP and/or LBP in pregnant Nepalese women using a cross-sectional design (paper II). As part of this study, we conducted a methodological sub-study where the reliability, validity and test–retest reliability of the Nepali PGQ were examined with a subset of the participants (paper I). In Study 2, the feasibility of performing a PFMT program in pregnant Nepalese women was assessed by a feasibility study (paper III; Figure 4).

Figure 4. Inclusion of 1,599 pregnant Nepalese women.

4.2 Study settings

The data collection in both studies was carried out at Dhulikhel Hospital. For the prevalence study (paper II), this was supplemented by additional data collection at KIST Hospital. The departments of obstetrics and gynaecology at Dhulikhel and KIST Hospitals offer highly specialised care in obstetrics and gynaecology services. Antenatal consultations are provided to around 50 pregnant women per day at Dhulikhel Hospital, and around 30 at KIST Hospital. Approximately 3,500 live births are seen at Dhulikhel Hospital each year, and 1,200 at KIST Hospital.

Dhulikhel Hospital and KIST Hospital are located in the same province but in different districts (Figure 5). Both hospitals are situated in urban municipalities. Dhulikhel Hospital is located in the Kavrepalanchowk district, 30 km northeast from Kathmandu Valley. Dhulikhel Hospital serves a significant population from rural areas, as the Kavrepalanchowk district includes five urban and six rural zones (2). KIST Teaching Hospital is located in Kathmandu Valley in the Lalitpur district, which has three urban and three rural zones. It provides services mostly to a population residing in Kathmandu Valley (2).

Figure 5. Map of rural and urban municipalities in Lalitpur and Kavrepalanchowk districts.

4.3 Samples

Inclusion and exclusion criteria

For both Study 1 and Study 2, Nepali-speaking pregnant women attending antenatal check-ups at the hospitals were eligible for recruitment and included

after filling in an informed consent. The only inclusion criteria were that they were willing to participate and could understand and speak Nepali. For Study 2 (paper III), the women had to be at ≤ 16 weeks of gestation.

For the methodological sub-study (paper I) in Study 1, only women with verified PGP after clinical examination were included. In Study 1, the women answered the question: "Have you had any musculoskeletal pain in the past four weeks?" If they answered "yes", the women were asked to indicate the location of their pain on a body chart. The pain site was validated by asking the women to point to the site of the pain on their body. If the women pointed to their pelvis (below L5), they were then examined by a physiotherapist. The criterion for PGP was pain over the pubic symphysis or sacroiliac joints, reproducible by the P4 test, ASLR test, provocation of the long dorsal sacroiliac ligament or the modified Trendelenburg test (30, 57-59) (Table 2). The P4 test and at least one of the other clinical tests had to be positive for each woman to be included.

For paper II, the women were supposed to be clinically examined, but as it was not feasible to examine all the women or to perform all the tests in the women who were examined. Even though the women's pain was located to the pelvic area, the pain might be referred from the lower back. Hence, in paper II, verified PGP was not an inclusion criteria and we probably have included women with PGP and/or LBP.

Table 2. Description of clinical tests to verify pelvic girdle pain.

Clinical test	<i>Posterior pelvic pain provocation test</i>	<i>Active straight leg raise test</i>	<i>Pain provocation of long dorsal sacroiliac ligament</i>	<i>Pain provocation of the symphysis pubis by modified Trendelenburg test</i>
Description*	Performed in supine position with 90 degrees of hip and knee flexion on the tested side. The contralateral pelvis was stabilised by the examiner's hand over the anterior superior iliac spine. Light manual pressure was applied on the flexed knee along the longitudinal axis of the femur.	Performed in supine position with straight legs and the feet 20 cm apart. The women were asked to raise one leg above the couch and to score how difficult it was to raise the leg on a six-point scale, from 0 = not difficult at all to 5 = unable to do.	Performed in a side-lying position with slightly flexed hip and knee joints. The assessor palpated the long dorsal sacroiliac ligament caudal to the posterior-superior iliac spine.	Standing on one leg, the subject lifted the other leg to 90 degrees of hip and knee flexion.
Positive test	When the patient felt a familiar, well-localised pain deep in the gluteal area on the provoked side.	When the patient had difficulty or was unable to raise the leg.	When the palpation provoked pain.	When standing on one leg provoked pain in the symphysis pubis.

* the tests were performed on both sides

Women in Study 1 were excluded if they had a history of spinal fracture or surgery or psychiatric diagnosis. In Study 2, women with pregnancy-related complications such as pre-eclampsia, risk of miscarriage, vaginal bleeding or fever were excluded.

4.4 Data collection

The data for Study 1 were collected from May 2016 to May 2017, including data collection for the methodological study (paper I) from May 2016 to December 2016. The data included in Study 2 were collected from May 2017 to April 2018 (paper III; Figure 4). Typically, the women visited the obstetrics and gynaecology department for antenatal consultations without appointment. Eligible women were contacted by one of two research assistants (one physiotherapist and one trained public health practitioner) at the antenatal waiting hall, where they waited for a consultation with a gynaecologist or a nurse-midwife. The research

assistants informed the women individually about the study, and those willing to participate were recruited. After the women had signed the informed consent, the research assistants verbally presented the questions from the questionnaire to the women and recorded the answers using an electronic device.

4.5 Translation and adaptation of the Nepali Pelvic Girdle Questionnaire

The translation and cross-cultural adaptation process into the Nepali language included forward translation, synthesis, backward translation, expert committee review and pretesting (165, 166). The English PGQ was forward translated into Nepali by a professional translator and a physiotherapist, followed by a synthesis process to obtain a consensus-based forward translation (paper I). The synthesised forward-translated version was back-translated into English by a professional English teacher and a health professional. Discrepancies between the various versions were resolved by an expert committee to achieve conceptual equivalence between the pre-final Nepali PGQ and the English PGQ. The pre-final version was pretested in 30 pregnant Nepali-speaking women. The comprehensiveness of, and potential difficulties in answering, the questionnaires were discussed. None of the women had major comments except for small wording or spelling corrections. The final version of the Nepali PGQ was then subjected to further testing for reliability and validity in Nepalese pregnant women with PGP (paper I).

4.6 Measurements

The variables reported in the three papers are presented in Table 3.

Table 3. Sociodemographic and condition-related variables of papers I, II and III.

Variable	Measurement unit	Paper I	Paper II	Paper III
Sociodemographic factors	Age	Years	x	x
	Height	Cm	x	x
	Weight	Kg	x	x
	Ethnicity	Brahmin / Chhetri / Newar / Tamang / Magar / Dalit / Others	x	x
	Place	Urban / Rural		x
	Education	No education / Primary ≤ 5 / Lower secondary 6–8 / Secondary 9–10 / Higher secondary 11–12 / Bachelor and above ≥ 13	x	x
	Monthly income	No income / Less than \$76 / \$76–153 / >\$153	x	x
	Occupation	Housewife / Agriculture / Business / Employed / Others	x	x
	Marital status	Living with husband / Husband working away from home / Divorced	x	x
	Type of family	Husband and children (nuclear) / Parents-in-law, husband and children (joint) / Grandparents, parents-in-law, husband and children (extended)	x	x
	Number of family members	Number	x	x
	Household work	Washing, cleaning, cooking / Childcare / Animal care / Fetching water	x	x
Pregnancy factors	Number of pregnancies	Number	x	x
	Parity	Number	x	x
	Gestation	Weeks	x	x
Workload Factors	Hours awake	Hours	x	x
	Rest during work	Hours	x	x
	Field work	Yes / No	x	x
	Type of field work	Farming / Grass cutting / Branch cutting / Fetching water	x	x
	Working position	Sitting or squatting / Standing or bending forward	x	
	Prolonged sitting or standing	Hours	x	

Table 3 continued.

Variable		Measurement unit	Paper I	Paper II	Paper III
Pain-related Factors	Pain (worst pain)	Numeric pain rating scale; 0 (no pain) – 10 (worst imaginable pain)	x	x	x
	Pain (evening pain)	Numeric pain rating scale; 0 (no pain) – 10 (worst imaginable pain)	x	x	x
	Pain frequency	On some days / Most days / Every day	x	x	x
	Specific pelvic pain location	Sacrum / Sacroiliac joints / Symphysis pubis	x	x	x
	LPB and/or PGP limiting/changing activity for more than one day	Yes / No	x	x	x
	Concerned if PGP and/or LBP will disappear after delivery	Numeric rating scale: 0 (not concerned) – 10 (extremely concerned)	x	x	x
	LPB and/or PGP disappear after delivery	Yes / No	x	x	x
Condition-related factors	Oswestry Disability Index (ODI)	0–100 (0 = no disability, 100 = maximum disability)	x	x	x
	Pelvic Girdle Questionnaire (PGQ)	0–100 (0 = no problem at all, 100 = to a large extent)	x	x	x
	International Consultation of Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ–UI SF)	0–21 (0 = no UI, 24 = high UI)		x	x
	Pelvic Organ Prolapse Symptom Score (POP-SS)	0–28 (0 = no prolapse symptoms, 28 = high symptoms of prolapse)		x	x
	Five-Item Edinburgh Depression Scale (EDS-5)	0–15 (0 = no depression symptoms, 15 = high depression symptoms)	x	x	x

Pain

The Numerical Pain Rating Scale (NPRS) was used to measure pain (167). The NPRS is an 11-point numeric scale that ranges from 0 (no pain) to 10 (worst imaginable pain), and has been found to be valid, reliable and appropriate for use in clinical practice with various patient groups (168). Pain was measured by asking about worst pain and evening pain intensity. Evening pain intensity was chosen since PGP has been shown to increase with activity (169). The NPRS was preferred over the visual analogue scale for its ability to be administered verbally (170). Verbal administration was of significance in this study, as our data was collected verbally. The NPRS has also been shown to be effective for use in individuals with low literacy (171).

Functional status

Functional status was assessed by the PGQ (172) and the Oswestry Disability Index (ODI) (173). The PGQ consists of 25 items, with 20 items related to activities and five items related to symptoms, and is a reliable and valid tool for measuring PGP (172, 174). Activity items include difficulty with dressing, standing, bending, sitting, walking, climbing stairs, doing housework, carrying objects, getting up, sitting down, pushing a shopping cart, running, sporting activities, lying down, rolling in bed, sex and pushing something with a foot. Symptom items incorporate morning and evening pain, extent of the feeling of legs giving way, the need to do things more slowly, and sleep interruption due to PGP. Each item is scored from 0 (not at all) to 3 (to a large extent) and summed, up to a maximum total score of 75, which then is re-calculated into a percentage score from 0 to 100 (worst possible). The two items for sex and physical activity have an option of not applicable. If the respondent chooses the not applicable option, the maximum score of these questions (three or six points) is deducted from the total score before converting into percentage scores. Activity and symptom subscales can be separately calculated as percentage scores for the 20 activity items and five symptom items. The PGQ is easy to use, takes around three minutes to complete and can be used in research and clinical practice (172). The Nepali version of the PGQ (paper I) was used in all three papers.

The ODI is a reliable and valid tool for assessing functional limitations in patients with LBP (173). The ODI consists of ten items that cover different aspects of functioning: pain intensity, self-care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. Each item is scored from 0 (no disability) to 5 (severe disability), with higher values representing greater disability. Item scores are summed and transformed to a percentage score from 0 to 100 (where 100 represents the greatest possible disability). The ODI has four versions; we used the modified ODI version 2.0, as it has been recommended by the original authors of the ODI (173, 175, 176). The Nepali ODI has been shown to have acceptable reliability in patients with LBP (177).

Pelvic floor disorders

The POP Symptom Score (POP-SS) tool was used for assessing POP (178), and the International Consultation of Incontinence Questionnaire–UI Short Form (ICIQ–UI SF) was used for assessing UI (179).

The POP-SS is a brief, reliable and valid questionnaire recommended for use in research and clinical practice (178). It measures POP symptoms and consists of seven items: the feeling of something coming down or in the vagina, uncomfortable feeling or pain in the vagina that worsens when standing, heaviness or dragging feeling in the lower abdomen, heaviness or dragging feeling in the lower back, need to push to empty the bladder, feeling that the bladder has not emptied completely, and feeling that the bowel has not emptied completely (178). Each item is scored from 0 to 4, with a total score ranging from 0 to 28, where a higher score reflects more symptoms.

The ICIQ–UI SF questionnaire is a short, robust, reliable and valid measurement for assessing UI (179). It consists of four items that assess the frequency, type and amount of UI and its impact on quality of life. The ICIQ–UI SF score ranges from 0 to 21, where a higher score implies a greater level of symptoms.

Depression

The five-item Edinburgh Depression Scale-5 (EDS-5) is a reliable and valid tool for assessing depression symptoms in women from the general population (180). The EDS-5 is a short matrix version of the ten-item Edinburgh Postnatal

Depression Scale (EPDS-10), which was developed to detect postnatal depression (181) and is highly correlated with the EPDS-10 (180). The EDS-5 measures depression symptoms and evaluates five dimensions: feeling sad or miserable, anxious or worried, unhappy, blamed unnecessarily, and looking forward to enjoyment. Each item is scored from 0 to 3, with the total score ranging from 0 to 15, and a higher score indicating a higher symptom level. The EDS-5 has cut-off values of ≥ 7 for moderate symptom levels and ≥ 8 for high symptom levels (180).

The POP-SS and ICIQ-UI SF underwent forward translation, backward translation and synthesis, while the EDS-5 underwent only forward translation. Thereafter, the POP-SS, ICIQ-UI SF and EDS-5 went through pilot testing in 30 pregnant Nepali-speaking women. The women were asked to provide comments regarding the language, such as wording and ambiguity.

4.7 Development of a pelvic floor muscle training program

Based on evidence from high-income countries (160, 182, 183), we developed a PFMT program that was adapted to a Nepalese context. The program consisted of two parts: supervised PFMT at Dhulikhel Hospital and daily home PFMT. Educational material was also developed, consisting of an illustrative video (<https://youtu.be/XsDpfq10JMI>; Figure 6), a leaflet (Figure 7) and an exercise diary (Figure 8).

Figure 6. Illustration of pelvic floor muscle contraction from the educational video.

Low sitting with crossed legs

Standing with support

Side-lying

Instructions

Pelvic floor muscle lift prior load lifting.

Not to push during defecation.

Rest in between work.

Pelvic Floor Muscle Exercises During Pregnancy

Pregnancy brings major changes in the body. Because of pregnancy women can have a long lasting problems like pelvic organ prolapse and urinary incontinence due to the bodily changes that have occurred.

Because of pelvic organ prolapse and urinary incontinence women suffer from urine leakage, smelly, pain and discomfort. This might influence on daily activities and sex life.

To prevent from pelvic organ prolapse and urinary incontinence pelvic floor muscle exercises should be performed.

How to perform pelvic floor muscle exercise?

Contract, lift, and hold the pelvic floor muscles for 3 sets, 10 repetitions with 2 minutes rest in between.

Pelvic floor muscle exercises can be performed in different positions.

High sitting

Standing

Low sitting

Figure 7. Educational leaflet with illustrations of exercise positions.

PELVIC FLOOR MUSCLE EXERCISE DIARY

ID No.

Date

Instructions for performing pelvic floor muscle exercises

Contract, lift, and hold the pelvic floor muscles for 3 sets, 10 repetitions with 2 minutes rest in between.

Perform this
exercise daily

Please fill this diary daily

Please tick (☑) if you completed 30 lifts

Please (X) if you did not complete 30 lifts

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1							
Week 2							
Week 3							
Week 4							
Week 5							
Week 6							
Week 7							
Week 8							
Week 9							

Figure 8. Exercise diary.

Initially, the women were individually taught how to contract the PFM. If possible, electromyography (EMG) biofeedback was used to ensure correct contraction. Thereafter, the women were referred to participate in groups to perform supervised PFMT. The women were then encouraged to perform the PFMT daily at home.

4.8 Statistical analysis

For all three papers, descriptive data were presented as mean (standard deviation [SD]) if normally distributed, median (minimum–maximum or interquartile range [IQR], 25th and 75th percentiles) if skewed, and as numbers and percentages if categorical. The level of statistical significance was set to $p < 0.05$. The data were analysed using SPSS software version 22.

In paper I, reliability was assessed using Cronbach's alpha for internal consistency, and intraclass correlation coefficient (ICC_{2.1}) using a two-way random effects model for test–retest reliability. A Cronbach's alpha between 0.7 and 0.95 indicates good internal consistency (184). Paired-sample t-tests were used to assess the differences between test and retest scores. The standard error of measurement (SEM) was calculated as $SD_{diff} / \sqrt{2}$. The SEM was used to calculate the smallest detectable change ($SDC_{95\%} = SEM \times 1.96 \times \sqrt{2}$), indicating a real change beyond measurement error with 95% certainty (184). For construct validity, Pearson or Spearman rank correlation coefficients were used to assess the correlation of the nine a priori formulated hypotheses. Seven of nine hypotheses (>75%) had to be confirmed for acceptable construct validity (184, 185).

In paper II, univariate and multivariate logistic regression presented as odds ratios (ORs) were used to analyse the associations between independent variables and PGP and/or LBP. Prior to the logistic regression analysis, the independent variables were tested for collinearity, and correlations greater than 0.7 were considered to be one-dimensional, with only one of the variables being kept in the analyses. Following this, we analysed the associations between independent predictive variables and PGP and/or LBP using Mann–Whitney U or Chi-square tests, depending on whether variables were

continuous or categorical. Variables with p value ≤ 0.25 were included in the multivariate regression model. In the multivariate regression model, we used a backward stepwise technique, where variables with p value > 0.05 were eliminated stepwise from the model until only variables with significant ORs remained. The variables in the final model were checked for pair-wise interactions.

In paper III, feasibility was assessed in terms of recruitment capability, sample characteristics, data collection procedures, outcome measures and acceptability of the PFMT program. Acceptability of the PFMT program was assessed by attendance at four or more supervised PFMT hospital visits, adherence to daily PFMT recorded in the exercise diary, and the women's experiences of attending the program. Mann–Whitney U or Chi-square tests were used to analyse differences in the sociodemographic and clinical variables between women attending and not attending at least four PFMT visits, depending on whether variables were continuous or categorical.

4.9 Ethics

Ethical approval was obtained from the Norwegian Regional Ethics Committee (REK Nord, 2015/2209), the Nepal Health Research Council Ethical Review Board (112/2016) and the Institutional Review Committee of Kathmandu University School of Medical Sciences/Dhulikhel Hospital (25/16), Nepal. Verbal and written informed consent was obtained from the participants.

5 MAIN RESULTS

The sociodemographic and questionnaire data used in all the papers are shown in Table 4.

5.1 Paper I

Transcultural adaptation, test–retest reliability and validity of the Nepali version of the Pelvic Girdle Questionnaire

The translation and adaptation process of the English PGQ to Nepali PGQ resulted in minor modifications due to linguistic differences and lack of applicability to the Nepalese daily lifestyle. Item 9, “climb stairs”, was reworded to “climb up and down stairs”; item 14, “push a shopping cart”, was modified to “push object with hand”; and item 15, “run”, was changed to “walk fast”.

The internal consistency, test–retest reliability and construct validity of the Nepali PGQ were assessed in 111 pregnant women. The participants’ mean age was 25 years ($SD = 4$) and the mean gestational week was 25 ($SD = 10$). The Nepali PGQ demonstrated good internal consistency ($\alpha = 0.83$) and acceptable reliability ($ICC_{2,1} = 0.72$). Even though the Nepali PGQ total score showed acceptable measurement error ($SDC_{95\%} = 18.6$ points), a large measurement error was observed in the PGQ symptom subscale ($SDC_{95\%} = 25.5$ points). Regarding construct validity, seven out of nine a priori formulated hypotheses were confirmed. No floor or ceiling effects were found for the Nepali PGQ.

Our findings suggest that the Nepali PGQ is a reliable and valid tool for assessing PGP in pregnant Nepalese women, even though a large measurement error did emerge. The Nepali PGQ can be used in clinical settings and for research purposes in evaluating PGP in pregnant Nepalese women.

Table 4. Sociodemographic and clinical variables of the pregnant women included in papers I, II and III (n = 1,537).

Variables	Paper I	Paper II	Paper III
Age, years, mean (SD)	25 (4)	25 (4)	25 (4)
Gestation week, mean (SD)	25 (10)	24 (10)	10 (3)
Number of pregnancies, median (IQR)	1 (1–2)	2 (1–2)	1 (0–1)
Parity, n (%)			
0		751 (58)	170 (68)
1	-	461 (36)	78 (30)
≥2		72 (6)	5 (2)
Body mass index, kg/m ² , mean (SD)	26 (4)	25 (4)	23 (4)
Type of family, n (%)			
Nuclear (husband and children)		593 (46)	89 (35)
Joint (parents-in-law, husband and children)		691 (54)	164 (65)
Family members, mean (SD)	-	5 (3)	-
Ethnicity, n (%)			
Brahmin		244 (19)	62 (25)
Chhetri		231 (18)	41 (16)
Newar		283 (22)	72 (28)
Tamang	-	267 (21)	35 (14)
Magar		54 (4)	7 (3)
Dalit		76 (6)	11 (4)
Others		131 (10)	25 (10)
Participant's education, years, n (%)			
No education	6 (5)	113 (9)	8 (3)
Primary (≤5)	7 (6)	148 (11)	19 (8)
Secondary (6–12)	75 (67)	818 (64)	172 (68)
Bachelor and above (≥13)	23 (21)	205 (16)	54 (21)
Participants without monthly income, n (%)	86 (77)	1100 (86)	195 (77)
Occupation, n (%)			
Housewife		1160 (90)	251 (99)
Business		114 (9)	13 (5)
Employed	-	124 (10)	45 (17)
Others (labour, student, retired)		26 (2)	7 (2)
Household work, n (%)			
Washing, cleaning, cooking		1284 (100)	253 (100)
Childcare		451 (35)	77 (30)
Animal care	-	207 (16)	36 (14)
Fetch water		463 (36)	77 (30)
Field work, n (%)	-	195 (15)	61 (24)
Rest in between work, n (%)	-	436 (34)	22 (9)
PGP and/or LBP, n (%)	-	432 (34)	77 (54)
POP-SS, median (IQR)	-	0 (0–3)	0 (0–2)
ICIQ-UI-SF, median (IQR)	-	0 (0–0)	12 (8)
EDS-5, median (IQR)	2 (0–5)	2 (0–4)	3 (1–6)

SD: standard deviation; IQR: interquartile range (25th–75th percentiles)

USD: United States dollars; LBP: low back pain; PGP: pelvic girdle pain; POP-SS: Pelvic Organ Prolapse Symptom Score; ICIQ-UI SF: International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form; EDS-5: Edinburgh Depression Scale five-item version

5.2 Paper II

Prevalence and severity of pregnancy-related PGP and/or LBP and their associated factors in Nepalese women

The prevalence and severity of PGP and/or LBP in pregnant Nepalese women were examined by a cross-sectional study of 1,284 pregnant women. The participants' mean age was 25 years (SD = 4) and the mean gestational week was 24 (SD = 10). No differences were found between the samples from the two hospitals. More than half (58%) of the women were nulliparous. The reported prevalence of pregnancy-related PGP and/or LBP in Nepalese women was 34%. Our results also showed that among the women who reported musculoskeletal pain (49%), the majority (69%) reported PGP and/or LBP. Among the women who reported PGP and/or LBP, more than half (65%) had a positive P4 test, and 41% had a positive ASLR test.

The evening pain intensity was reported to be high, with a mean of 6 (SD = 2). The median disability total score was 20 (IQR 10–32) for the Nepali PGQ and 30 (21–38) for the Nepali ODI. Twenty-four percent of the women had pain most days, and one third reported limitation of their ability to perform usual activities for more than one day due to PGP and/or LBP. Although 50% of the women with PGP and/or LBP either were unsure or did not believe that their pain would disappear after delivery, concern about the pain was reported to be low (median 2, IQR 0–4). Multivariate analysis showed that women with higher BMI, POP symptoms and husbands with higher education were significantly more likely to have pregnancy-related PGP and/or LBP.

In summary, we found that PGP and/or LBP are prevalent in pregnant Nepalese women. Even though women reported severe pain intensity, they experienced low disability. Despite the women's poor belief in recovery of LBP and PGP after delivery, they reported low concern about their pain. Women with higher BMI, POP symptoms and husbands with higher education were significantly associated with PGP and/or LBP.

5.3 Paper III

Feasibility of a PFMT program in pregnant Nepalese women

An antenatal PFMT program was developed and consisted of two parts: attending at least four supervised PFMT visits at Dhulikhel Hospital and performing PFMT daily at home. First, the women were given information regarding the PFMT program, teaching PFM contraction using EMG biofeedback, and supervising PFMT either in groups or individually at the first visit. The women were informed to perform daily PFMT at home and to visit the hospital for at least four PFMT visits. The program was based on evidence from developed countries (160, 182, 183) and adapted to the Nepalese context. The educational material developed for the study consisted of a video (<https://youtu.be/XsDpfq10JMI>), leaflet and exercise diary (Figure 6, 7, 8 and Appendices 1 and 2).

A total of 315 women were eligible for the study; 42 declined to participate in the PFMT program, 18 were excluded because of pregnancy-related complications and four did not meet the inclusion criteria. Thus, 253 women were included in the PFMT program, with a mean age of 25 years (SD = 4) and mean gestational week of 10 (SD = 3). We found that the participants had no difficulty in answering the questionnaires. However, after they responded to the questionnaires, we experienced that some participants were hesitant to attend the PFMT classes, mainly because they were worried that it would be too late for them to walk home or that their public bus might leave.

Among the 253 women included in the study, 144 (57%) attended at least four PFMT visits. The majority (92%) of the women resided in urban areas and most (79%) came from the same district where the hospital is located. The only significant difference observed in the sociodemographic factors between the women who attended the PFMT visits and those who did not was the residing district ($p=0.007$), with more women from urban areas attending at least four PFMT visits. No significant differences were found in the symptoms of UI (0.89) and POP (0.44) between the women attending and those not attending at least four PFMT hospital visits. Half of the women adhered to 50% to 100% of daily

PFMT at home. The strongest factor reported in compliance with the PFMT at home was to prevent POP (52%), followed by the feeling of importance for health (44%) and to prevent UI (13%). Lack of time (49%), forgetting to perform PFMT (38%) and health problems (35%) were the main reasons for not being able to perform the PFMT.

This study showed that it is feasible to perform a PFMT program in pregnant Nepalese women. More than half of the women attended the PFMT visits and half of the women performed PFMT at home. Our experiences gave us the impression that supervised PFMT visits and the educational material motivated the women to perform the PFMT program.

6 GENERAL DISCUSSION

6.1 Methodological considerations

The results in this thesis should be interpreted in the context of some methodological considerations, which are presented below.

6.1.1 Design and methods

For the methodological study in paper I, we generally followed the guidelines developed by Guillemin to ensure a thorough adaptation process, although we also added the synthesis stage from the guidelines developed by Beaton (165, 166). The synthesis stage was included because we assumed that it might add value by resolving variations in the forward translations. Some wording and terminology differences did arise in the forward translations, which the translators resolved by consensus. Because the translation process of the Nepali PGQ followed a standardised transcultural adaptation procedure, we expect that the Nepali PGQ is conceptually equivalent to the original PGQ.

To ensure high methodological quality of the examination of measurement properties of the Nepali PGQ, we followed the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines (184, 185). We tested the reliability and validity of the Nepali PGQ, but responsiveness was not included as we did not collect data prospectively. This remains to be investigated in a future study. A potential weakness in paper I could be the short time interval between test and retest, which was approximately five hours. The short test–retest interval in the present study was necessary as most of the women lived far away from Dhulikhel Hospital, making it unlikely that they would visit the hospital only for a retest. An alternative would have been to wait a month and see whether the women met for an antenatal follow-up visit at Dhulikhel Hospital. However, since the women were pregnant, a month's time could have affected the stability of their condition. Such a short time interval might lead to recall bias. However, as the comprehensive questionnaire contained a long list of questions, we assumed it was unlikely that the women would remember the responses they previously

gave to each (186). To date, no standard rules have been established for the length of time between a test and retest (186). A study that conducted test–retest at two different time intervals of two days and two weeks did not show significant differences in test–retest reliability (187). Similarly, PGQ studies conducted with test–retest intervals of seven days, two days and ≤ 30 days did not show any significant differences in test–retest reliability (174, 188, 189).

We decided that a cross-sectional design was reasonable to use in paper II, as we aimed to assess the prevalence of PGP and/or LBP in pregnant Nepalese women, and to examine the associations between PGP and/or LBP and different sociodemographic and condition-related variables (190, 191). However, since this study is a one-time measurement of outcome and exposure, we cannot interpret the findings in terms of cause–effect relationships (191).

In paper III, we wanted to explore whether a PFMT program was feasible for pregnant Nepalese women; as a result, we designed it as a feasibility study. In conducting the study, we adhered to the definition by Eldridge et al. (192) of a feasibility study as “a study conducted to determine whether something can or should be done, and if so, how”. The recommendation is to perform a feasibility study before performing a pilot RCT, in order to evaluate the practicality of implementing all or part of an intervention and other processes in a larger future RCT study (192). Since no RCTs on PFMT have been published in Nepal, an RCT is needed to investigate the effectiveness of PFMT in Nepalese women. The results of a feasibility study measuring the acceptability of the PFMT program could guide the design of a future RCT.

One strength is that we used large samples in all the three papers. In paper I, we included a sample of 111 pregnant women, consistent with the COSMIN guidelines, which recommend a sample minimum of 100 to attain excellent methodological quality (184, 185). In paper II, our sample relied on the number of women that we were able to include over the course of one year. Since we were assessing the associations of many independent variables with PGP and/or LBP, a large sample size was required. We included 20 independent variables, requiring at least 200 participants with pregnancy-related LBP and/or

PGP, as per the ‘rule of 10’ for association analyses (193). Hence, the sample of 1,284 pregnant women was considered sufficient for assessing the associations between independent variables and PGP and/or LBP. For the feasibility study (paper III), we included a large sample of 315 women. Such a large sample size is not normally needed for feasibility studies (194, 195); however, we expected a high dropout rate as most of the women visiting Dhulikhel Hospital travelled great distances and did not come for specific appointments.

In line with our expectations, we found that in the initial stage of the study, many women did not attend the PFMT visits. Consequently, we provided regular reminders via telephone about the PFMT visits, and included travel reimbursement for the women who attended at least four visits, both of which might have increased attendance.

6.1.2 **Data collection**

Due to high illiteracy in Nepal, we recorded data from questionnaires through face-to-face interviews. Two research assistants carried out the interviews. This might potentially have influenced the responses, as different interviewer personalities and characteristics might generate different response patterns (196). The importance of careful training and response monitoring to minimise inter-interviewer variation has previously been reported (197). Thus, to avoid bias, the research assistants in our study were thoroughly trained prior to the data collection, and clearly instructed to ask the same questions in a standardised way, without discussing any responses. In previous international studies on women with PGP, data have been collected by having the participants fill in the questionnaires themselves (69, 172, 198). It is unclear how much the results may be influenced by different data collection procedures, although one study has shown no difference in patient-reported outcomes between self-completed versus assisted modes of administration (199).

Other aspects such as cultural norms and ‘eagerness to please’ might have influenced our results (200-202). Nepalese women are generally expected to provide a socially desirable response, which makes them vulnerable to ‘eager

to please' bias (203). In addition, some of the outcome measures contained sensitive questions (such as about sex life), and data collection through personal interviews might have led to underreporting of such problems. Further, our data collection might have led to over-reporting on other questions, such as the number of PFMT sessions reported in the exercise diary in paper III. The findings in paper III that some women reported inconsistency in the PFMT performed might be an 'eager to please' response. Therefore, the results regarding sensitive questionnaire questions and the exercise diary should be carefully interpreted.

6.1.3 Measurements

When selecting the measurements for this study, we wanted to use standardised questionnaires that had undergone reliability and validity assessment, not only internationally but also for use in a Nepalese population. We found, however, few relevant questionnaires validated in Nepal. The PGQ, ICIQ-UI SF and POP-SS were considered to be the best measurements for assessing pelvic girdle pain and pelvic floor disorders in pregnant women, and were therefore translated into the Nepali language in the first phase of this study.

We decided to use the PGQ to measure pelvic-related pain and disability in this study, as this is the only condition-specific questionnaire for women with PGP during and after pregnancy (172). Moreover, the PGQ has been recommended as a primary tool for studies on PGP and/or LBP (204). However, since the PGQ had not been previously used in Nepal, we also included the Nepali version of the ODI (177). The Nepali ODI has shown acceptable reliability in Nepalese people with LBP (177) and has been used in a previous study in Nepal (205). Moreover, the ODI has been widely used in pregnancy-related PGP and LBP studies (34, 35, 50, 206-208) and has shown good internal consistency, test-retest reliability and construct validity for pregnant women with PGP (174). Since we probably have included women with both PGP and LBP, the use of both questionnaires enabled us to cover disabilities from both conditions. We also included the Nepali version of the NPRS has shown good reliability, validity and responsiveness in Nepali subjects with musculoskeletal pain (209).

The POP-SS has the ability to detect the differences between symptomatic and asymptomatic POP (178), and it has been used in a multicentre RCT to assess whether PFMT would be effective in women with mild to moderate anatomical prolapse (210). The POP-SS has been shown to detect changes in the symptom score of women who received PFMT (210). To our knowledge, no published reliable and valid questionnaires are currently available in the Nepali language for assessing POP and UI symptoms, although a recent study validated specific questions for these conditions in Nepal (211). The validated questions (211) are similar to questions included in the POP-SS (210) and the ICIQ-UI SF (179).

To measure depression and anxiety, we used the EDS-5, since our participants were pregnant women. The Nepali version of the longer EPDS has been found to be a valid instrument for screening postpartum depressive symptoms in Nepalese women (212), and the EPDS has been shown to correlate strongly with the EDS-5 (180).

The POP-SS, EDS-5 and ICIQ-UI SF were also chosen for practical reasons, as these questionnaires are specific, short and simple to use (178-180). Research has reported that the fewer items in a questionnaire, the higher is the reliability of the questionnaire (213). One limitation of our studies is that the POP-SS, EDS-5 and ICIQ-UI SF have not undergone reliability and validity testing in pregnant Nepalese women. The reliability and validity of these tools were not tested due to time constraints. Even though these questionnaires were not used to measure the main outcomes in our studies, this lack is still a limitation.

Before the data collection, the comprehensive questionnaire package was pretested among pregnant women to gain feedback regarding wording and ambiguity. No major changes were recommended by the women regarding comprehension of the questions or the response format. We attempted to keep the questions short and simple and (where possible) avoid questions that required long-term recall, so that the women would not lack the attention or motivation to answer the questions (214). Since most of the questions required a recall period of less than four weeks, we consider the risk of recall bias to be low (215). By pretesting, avoiding long questions and avoiding questions with a

long recall period, we attempted to increase the reliability of the questionnaires.

6.1.4 Generalisability

The Nepalese women taking part in the prevalence study (paper II) came from two hospitals: one located in Kathmandu valley and the other located in Dhulikhel, 30 km away from Kathmandu. We recruited women from these two different hospitals for paper II because we hoped to include participants representing both urban and rural areas of Nepal. However, we did not succeed in recruiting enough women from rural areas to make this distinction. There were no significant differences in characteristics between the two samples of pregnant women. In paper III, only 8% of the women were from rural areas, and most who attended at least four PFMT visits lived near Dhulikhel Hospital. Consequently, our findings might be representative of Nepalese women living in urban areas.

In Nepal, urban areas comprise 17% of the population, and rural areas 83% (1). The socioeconomic and health statuses of the urban and rural populations differ widely (1). Compared to people from urban areas, people in rural areas have a low socioeconomic status with a high burden of physical workload, and often lack access to basic healthcare facilities (8, 216). Furthermore, the POP prevalence in Nepal has commonly been assessed in rural areas (12, 123, 124). Therefore, prior to this study, we expected that women from urban areas would differ from those in rural areas with respect to PGP and/or LBP, as well as for POP and UI. However, the women in our samples were different from the women included in previous studies from rural areas; for example, the women in our samples had a higher level of education and very few reported carrying heavy loads (12, 123, 124). This finding also indicates that our results cannot be generalised to women living in rural or remote areas of Nepal.

Another aspect influencing the generalizability and external validity of our results is the inclusion criterion of language skills. Cognitive and language skills have been shown to influence patient-reported outcome measures (186, 202). In our studies, the women had to be able to speak and understand the Nepali

language, which is the official and primary spoken language in Nepal (1). Female literacy rate is low in Nepal (57.4%) and a low literacy level might negatively affect a person's socioeconomic status, which can be a barrier to obtaining healthcare (4, 8). Since most of the women included in our samples had a secondary-level education, we cannot generalise our results to Nepalese women who are illiterate or have lower education.

Women with psychiatric diagnoses were excluded as they were assumed to lack the capacity for decision-making, potentially leading to inaccurate information or low quality of data. Exclusion of participants with psychiatric disorders is common in many studies (206, 217, 218). In addition, in paper III, pregnancy-related complications such as pre-eclampsia, risk of miscarriage, vaginal bleeding and fever were excluded because we used EMG biofeedback to teach PFM contractions at the first visit. Previous studies using EMG biofeedback for PFMT in pregnant women have only included healthy pregnant women (219-222). Since this was the first time EMG biofeedback was used at Dhulikhel Hospital, the gynaecologists preferred to be extra cautious; therefore, we included only healthy low-risk pregnant women to avoid any complications.

6.2 Discussion of the main findings

The results of the papers constituting this thesis have been discussed and compared with other studies in detail in the discussion section of each paper and will not be repeated in full. This section of the thesis will discuss the main findings in relation to previous research.

6.2.1 Cultural adaptation and psychometric testing of the Nepali version of the Pelvic Girdle Questionnaire (paper I)

Table 5 provides an overview of all the translated versions of the PGQ. Similar to the Polish, French-Canadian, and Brazilian-Portuguese versions of the PGQ, we had to change some wording and phrases in the Nepali PGQ (188, 223, 224). These modifications were necessary for the PGQ to be applicable to the

Nepali population while keeping the concept set forth in the English PGQ (166). As presented in Table 5, the acceptable reliability for the Nepali PGQ is comparable to other translated and validated PGQ studies of women with PGP (188, 189, 225, 226). Furthermore, the Nepali PGQ showed moderate internal consistency, which is similar to the English, Iranian and Brazilian-Portuguese PGQ versions (174, 188, 189). The internal consistency was slightly higher in the Polish, French-Canadian, Spanish, Swedish and Japanese PGQ versions (224-228).

Our results also show that the measurement error (in terms of the SDC) in the Nepali total PGQ was slightly larger than in other PGQ versions (174, 188, 189, 229) (Table 5). Despite the short test–retest time interval in our study, this difference might be due to many activities during the day the women visited the hospital, including consultation with gynaecologists and midwives, laboratory testing, ultrasounds and blood tests. All these activities required moving from one place to another, which could have led to more pain and symptoms at the retest measurement.

The construct validity in the Nepali PGQ was acceptable and similar to previous studies (174, 188, 225-230). One fourth of the hypotheses were not confirmed. For example, we hypothesised that a moderate to high correlation would be found between the PGQ subscales and the Patient Specific Functional Scale (PSFS), but the correlation turned out to be weak. One possible explanation is that the PSFS only assesses functional limitation, while the PGQ assesses both symptoms and activity limitation. Moreover, the PSFS measures generic activity limitation, whereas the PGQ is more sensitive and specific to the consequences of PGP (231).

Table 5. Measurement properties of the translated versions of Pelvic Girdle Questionnaire (PGQ).

Author	Country	Language	n	Classification of PGP	Test-retest	ICC (Total PGQ)	Internal consistency (Total PGQ)	SEM	SDC	Hypothesis
Stuge et al. 2011	Norway	English, Norwegian	94	Pain location, clinical tests	7 days	0.93* 0.91\$	0.86	-	-	-
Grotle et al. 2012	Norway	English	87	Pain location, clinical tests	7 days	0.93	0.86* 0.68\$	5.33	14.8	Confirmed (ODI, DRI, FABQ, PCS, SF-36)
Rejano-Campo et al. 2017	Spain	Spanish	125	Pain location	7–10 days	0.96	0.96	3.23	-	Confirmed (ODI, FABQ, PCS, SF-36, VAS)
Girard et al. 2018	Canada	French-Canadian	82	Presenting PGP	48–72 hours	0.84	0.93* 0.67\$	-	-	Confirmed (ODI, NRS)
Starzec et al. 2018	Poland	Polish	49	Pain location	-	-	0.92	-	-	-
Fagundes et al. 2018	Brazil	Brazilian-Portuguese	100	Clinical tests	48 hours	0.85	0.83	5.0	11.63	Confirmed (RMDQ, WHOQOL-BREF)
Simoes et al. 2018	Brazil	Brazilian	157	Pain location, clinical tests	7 days	0.97	Good (rasch analysis)	3.83	10.80	Confirmed (pregnant women with and without PGP)
Gutke et al. 2019	Sweden	Swedish	177	Self-reported	-	-	0.96	-	-	Confirmed (ODI, NRS)
Rashidi Fakari et al. 2019	Iran	Persian	150	Clinical tests	≤30 days	0.83	0.87	2.53	6.98	Factor analysis
Yelvar et al. 2019	Turkey	Turkish	135	Clinical tests	7 days	0.98	0.98	-	-	Confirmed (VAS, ODI, NHP)
Shiagurumayum et al. 2019 (accepted)	Nepal	Nepali	111	Pain location, clinical tests	5 hours	0.72	0.83	6.7	18.6	Confirmed (ODI, NRS, PSFS, EDS-5)
Gamada et al. 2019 (accepted)	Japan	Japanese	40	Pain location, clinical tests	7–10 days	0.79	0.96	-	-	Confirmed (ODI, PGQ, DRI, PCS, SF-36)

* Activity subscale; \$Symptom subscale;

DRI: Disability rating index; EDS-5: Edinburgh Depression Scale-5, FABQ: Fear-avoidance beliefs questionnaire; ICC: Intraclass correlation coefficient; SEM: Standard error of measurement; NRS: Numeric rating scale; NHP: Nottingham health profile; ODI: Oswestry disability index ; PCS: Pain catastrophizing scale ; PSFS: Patient specific functional scale, RMDQ: Rolland Morris disability questionnaire; SDC: Smallest detectable change; SF-36: 8-item version of the 36 item short-form health survey questionnaire; VAS: Visual analogue scale; WHOQOL-BREF: World health organization quality of life-BREF

6.2.2 Prevalence and severity of pelvic girdle pain and/or low back pain in pregnant Nepalese women (paper II)

The prevalence estimate of 34% of women reporting PGP and/or LBP was lower than most other comparable studies (40, 50, 73, 206, 207, 217). Table 6 provides an overview of previous studies, showing a wide range of prevalence estimates, with studies reporting 31% to 90% for LBP, 2% to 74% for PGP and 25% to 86% for PGP and/or LBP (29, 30, 42, 50-52, 69, 198, 206, 217, 232, 233). The large disparities in the prevalence of PGP and/or LBP might be due to variations in definitions, study designs and inclusion criteria. The methods used for classifying PGP and/or LBP include a range of methods, such as self-reported questionnaires, pain drawings and clinical tests (Table 6). To diagnose PGP, the European guidelines recommend that the pain needs to be verified by clinical tests (30). Clinical testing of subjects is time-consuming and challenging; hence, most studies rely on self-reported pain location (Table 6), which limits the possibility to distinguish between PGP and LBP. Another aspect that has likely influenced our prevalence estimate is the operationalisation of PGP and/or LBP. Similar to Gutke et al. (198), we asked, “Have you had any musculoskeletal pain in the past four weeks?”, and only the women who answered yes were asked to mark their pain location on a body diagram. It might be that the responses could have been different if we had asked direct questions about pain in the lower back and pelvic areas (52, 69, 206, 207, 217, 233). Another potential reason for the lower prevalence estimates among Nepalese women is that they might have considered the pain a normal process of aging, similar to what was observed in a recent musculoskeletal pain survey (234).

Table 6. Studies reporting prevalence and severity of pregnancy-related PGP and/or LBP after 2015.

Study	Country	Design	n	Recruitment	PGP and/or LBP classification/measurements	Parity	Trimester or week of gestation (WoG)	Prevalence
Dunn et al. 2019	USA	Prospective cohort	288	Pregnant women attending antenatal visits at university community clinics, community health centres	Pain location, pain drawings, VAS	Nulliparous	>28 WoG	LBP: 77% PGP: 74%
Saxena et al. 2019	India	Cross-sectional	200	Pregnant women attending antenatal visits at tertiary hospital	Pain location, pain drawings, clinical tests, VAS	Mixed	8–36 WoG	LBP: 80% PGP: 2%
Starzec et al. 2019	Poland/Norway	Cross-sectional	264	Pregnant women attending birth schools, gym class, gynaecology outpatient clinics, state healthcare centres, yoga class, private midwives office	Pain location, pain drawings, NRS, PGQ	Mixed	12–36 WoG	Polish: PGP: 17%; LBP and PGP: 25% Norwegian: PGP: 19%; LBP and PGP: 37%
Backhausen et al. 2019	Denmark	Cohort study	513	Pregnant women, recruited from routine ultrasound scan	Pain drawings, LBP rating scale, RMD	Mixed	20, 32 WoG	LBP: 76% (20 WoG) 90% (32 WoG)
Manyozo et al. 2019	Malawi	Cross-sectional	404	Pregnant women attending low-risk antenatal visits at local health facilities	Self-reported LBP, ODI	Mixed	Mixed trimester	LBP: 62%
Shad et al. 2018	Pakistan	Cross-sectional	550	Pregnant women attending antenatal visits	Pain drawings, VAS, ODI	Mixed	Third trimester	Lumbopelvic pain: 41%
Sencan et al. 2018	Turkey	Cross-sectional	1,500	Pregnant women admitted to a prenatal care clinic in a secondary care hospital	Self-reported LBP, VAS, ODI	Mixed	Mixed trimester	LBP: 53.9%
Usman et al. 2017	Nigeria	Cross-sectional	309	Pregnant women attending antenatal clinic at hospital	Self-reported LBP/PGP	Mixed	Mixed trimester	LBP: 34.3% PGP: 57.6%
Gutke et al. 2017	UK, USA, Norway, Sweden	Cross-sectional, successive	869	Pregnant women	Pain location, pain drawings, NRS, PGQ	Mixed	30–38 WoG	PGP and/or LBP: 70–86%
Morino et al. 2017	Japan	Cross-sectional	275	Pregnant women attending antenatal check-up at obstetrics and gynaecology clinics	Self-reported LBP, pain drawings, NRS	Mixed	<12 WoG	LBP: 12 WoG: 59.1%; 24 WoG: 73.5%; 30 WoG: 72.9%; 36 WoG: 73.5%
Carvalho et al. 2017	Brazil	Cross-sectional	97	Pregnant women attending the prenatal low-risk program at the Centre for Women Care	Self-reported LBP	Mixed	Mixed trimester	LBP: 68%
Mahishale et al. 2016	India	Cross-sectional	457	Pregnant women at inpatient and outpatient department of obstetrics and gynaecology at tertiary care centre	Clinical tests, ODI, PGQ	Mixed	16–40 WoG	LBP: 31% Posterior pelvic pain: 65% Anterior pelvic pain: 15%
Sibbritt et al. 2016	Australia	Retrospective	1835	Pregnant women, selected from the National Medicare database	Self-reported back pain/PGP	Mixed	Mixed trimester	Back pain: 39.5% Pelvic pain: 16.3%

VAS: Visual Analogue Scale; NRS: Numeric rating scale; ODI: Oswestry Disability Index ; PGQ: Pelvic Girdle Questionnaire; RMD: Roland-Morris Disability Questionnaire;
LBP: Low Back Pain; PGP: Pelvic Girdle Pain

The pain intensity was higher in our study compared to that found in other similar studies (198, 233). In a multinational study, higher pain intensity was reported by women in the United Kingdom than by women in Norway, Sweden and the United States (198). The women in the United Kingdom had lower education levels than the other countries, which is similar to our sample where the majority had low levels of education. As education level has been found to be associated with symptom severity (235), the low level of education could be one reason for the higher reported pain intensity in the present study.

Despite higher pain intensity, we observed lower levels of disability when compared to most of the other studies in Table 5. In our study, we found a PGQ score of 20% and an ODI score of 30%. Possible explanations for these low levels of disability could be that most of our participants were at a mean gestation of 24 weeks, whereas the participants in the previous studies were in their third trimester (36, 41, 74, 198, 233, 236). Disability has shown to increase with the number of weeks of gestation (237).

Our results in Paper II showing that women with a higher BMI were more likely to report PGP and/or LBP is in line with most previous studies (51, 52, 69, 94). We also found that women with symptoms of POP were more likely to report PGP and/or LBP. This finding is contrary to what two previous studies have reported (238, 239). The difference in findings might be due to differences in populations and measurements.

Surprisingly, our study showed a positive association between women married to educated husbands and PGP and/or LBP. One potential explanation for this finding is that educated men frequently work far away from home, and this might lead to increased household work and strenuous physical workloads for the women (240). This assumption is supported by a study from Nepal conducted in the far western region, which showed that women in migrant households bear a higher physical workload than women in non-migrant households (240).

6.2.3 Pelvic floor muscle training in pregnant Nepalese women (paper III)

The present study finding that more than half of the women (57%) attended four or more supervised PFMT visits reflects higher attendance for PFMT than what two other studies have reported (48% and 29%) (182, 241). Adherence is a key factor in making a PFMT program adequate and effective, and it is crucial during both the supervised clinical phase of PFMT and the home phase (242, 243). In order to enhance adherence we included education, counselling, videos, leaflets and an exercise diary adapted to the Nepali culture and context, similar to other studies on PFMT (151, 244, 245). The use of educational material in our study may have positively influenced the adherence to PFMT. In line with our findings, a recent study reported that an educational class for antenatal mothers promoted patient motivation and adherence to PFMT (246). Moreover, in accordance with other studies, our participants received individual instructions and follow-up by either visits or phone calls (243, 247-250). Adherence is also associated with factors such as education and information about the importance of the pelvic floor, with ethnicity also playing a role (242, 251, 252). Integration of PFMT into daily activities has been strongly recommended (242) and was also strongly emphasised in our PFMT program.

In a recent study, one single PFMT session immediately postpartum was shown to be ineffective for improving UI (253). Shannon et al. (241) found a significant association between the number of visits and discharge from PFMT. If a patient attended six visits, it was likely that she would complete therapy (241). Since pregnant women in Nepal are recommended to attend four antenatal check-ups, we planned for at least four PFMT visits. We found that more than one visit seemed to benefit the women in terms of gaining the confidence to perform PFMT.

We concluded that the PFMT program was feasible and acceptable to perform, at least for those living within the district of the study site. Shorter distance between therapy location and patient residence, as well as more frequent UI leakage episodes, have been associated with improved PFMT adherence (182,

244). We also found that distance between the home and the hospital was a significant factor in whether a woman came for PFMT visits. In contrast to previous studies (182, 249, 254), where the participants were women with pelvic floor disorders, our study participants were pregnant women who primarily did not have POP or UI. We consider the adherence in this study to be good, considering that our participants did not visit because they suffered from pelvic floor disorders, but did report that POP prevention was the strongest motivating factor for performing PFMT. Interestingly, only 13% of the women reported UI prevention as a factor for performing PFMT. This could likely be due to low awareness of UI or because UI is not considered a major health complaint by the women in Nepal (136).

Similar to other studies, we assessed the acceptability of performing PFMT using attendance at hospital visits and PFMT adherence at home, recorded by exercise diary (182, 250). Our study showed large inconsistencies in reporting in the exercise diary: half of the women claimed to have performed 50–100% of daily PFMT at home, and 14–22% of the women over-reported their PFMT. We do not know the reasons for this over-reporting, but it might have to do with the impulse to give socially desirable responses, as Nepali culture demands that women be socially virtuous, leading to a tendency to describe themselves in favourable terms (203). Therefore, the results from the self-report diary must be interpreted carefully.

Self-efficacy, motivation and ability to perform correct PFM contraction have been shown to improve PFMT adherence (242, 252). Similar to several other studies, we used verbal instructions and biofeedback to teach the correct way to perform PFM contraction (160, 183). Biofeedback has been shown to be beneficial in educating patients on how to correctly perform PFM contractions (255, 256). Studies have demonstrated that 33% of women were unable to contract the PFMs properly, even after thorough one-to-one instruction (257). A recent study from Nepal also encountered challenges in teaching PFM contractions to Nepalese women using only verbal instructions and flyers (258, 259). Biofeedback is a supplementary method to motivate patients to perform the correct contraction and to achieve a stronger muscle contraction. However, a systematic review suggested that PFMT with biofeedback is no more effective than other treatments dealing with PFM function (260). In addition, according

to a more recent study, supplemental biofeedback for home PFMT did not increase the frequency of training (261). We included biofeedback because the observation of a contraction could be important for correct performance at the beginning of the treatment (262). In our study, we found that some women did not want the biofeedback, and some were too shy to watch the screen; as a result, we do not know how biofeedback influenced the success of the women's PFM contractions.

It is recommended that medical professionals keep patients informed in order to increase knowledge and teach the physical skills of PFM engagement (242, 246). Knowledge about PFMs and PFMT is scarce in Nepal (259). A study showed that less than 50% of the women had some knowledge about PFMT prior to participating in the study (263). For our PFMT program, we developed an informative video that was shown in the antenatal waiting area. The pregnant women often arrived for their antenatal check-up with their husband and/or mother-in-law, and they often watched the video together. POP is still stigmatised in Nepal, and men might choose to separate or even remarry if they discover that their wives have a pelvic floor disorder (6). Since most women need approval from their spouse or mother-in-law to seek healthcare, (264), we considered the video to be important to increase knowledge and understanding about PFMT. On the other hand, a recent study from the United States showed that the addition of an informational video did not improve patient preparedness or odds of attending PFMT (265). The authors of the study concluded that adherence behaviours and PFMT attendance are multifactorial and require further qualitative research to understand this issue in more depth. Our feasibility study is limited in that we did not perform in-depth interviews on the subject of the women's experiences of the PFMT program and the video.

One strength of this feasibility study is that we reported the PFMT program according to the Consensus on Exercise Reporting Template (CERT) (266). A recent review highlighted that PFMT parameters were not adequately or sufficiently reported in published RCTs, which currently guide clinical practice (267). The least frequently reported items were the provider of the intervention, the equipment used, the tailoring of the exercises, the rationale

behind the intervention, and adherence to the intervention. These factors, considered to be the biggest barriers towards PFMT adherence, were not taken into account by any of the studies included in the above-mentioned review (267). By describing our treatment program in detail, we aimed to encourage high implementation of the PFMT. This allows women in Nepal to receive an up-to-date, evidence-based intervention, and we also hope to establish a foundation for future effect studies. By reporting key components in the description of the PFMT program, we tried to ensure replicability and implementation in clinical settings and for research protocol descriptions and modifications.

7 Clinical implications and future studies

7.1 Clinical implications

The present results indicate that the Nepali version of the PGQ is a reliable and valid tool and can be used to assess PGP and/or LBP among Nepalese women. The results show that PGP and/or LBP are common problems in pregnant Nepalese women, highlighting the need for further research on how to prevent and treat PGP and/or LBP in Nepal.

Though PFMT is evidenced-based and recommended as first-line prevention and treatment of POP and UI, the Nepali government has primarily focused on surgical treatment for POP. Our findings show that implementing a PFMT program among Nepalese pregnant women is feasible. The results suggest that PFMT might be a promising intervention to treat and prevent pelvic floor disorders in Nepalese women. However, its effectiveness among Nepalese women needs to be documented.

Physiotherapy is a relatively new profession in Nepal, and these studies might increase the awareness of physiotherapy, especially in women's health in Nepal. In general, the present findings are of importance for healthcare providers working with pregnant Nepalese women.

7.2 Future studies

Since Nepal varies geographically, and our study population came mostly from urban areas, further research is needed to examine the prevalence of PGP and/or LBP in pregnant Nepalese women in rural and remote areas, also including assessment of the prevalence of PGP and/or LBP postpartum.

Studies assessing the feasibility of performing PFMT for pregnant women in remote areas of Nepal are needed. Even though the evidence for PFMT is good in high-income countries, it is lacking in Nepal. Studies evaluating the effectiveness of PFMT in pregnant Nepalese women are also necessary in order

to examine whether pelvic floor disorders can be prevented or reduced postpartum.

Drawing on the results and experiences from the current study, we presented recommendations for implementation and future studies in Paper III, in which we highlighted that PFMT programs should be conducted close to where women live, involve educated female community health volunteers for motivation and supervision, and include biofeedback for correct PFM contraction, if possible. The newly developed educational material can be a significant contribution for future studies and for implementation of PFMT programs in Nepal.

8 Conclusions

The main conclusions of this thesis are:

- The Nepali PGQ was found to be a reliable and valid tool for assessing PGP and/or LBP in pregnant Nepalese women.
- PGP and/or LBP were commonly reported in pregnant Nepalese women. The reported pain intensity was found to be relatively high, while the disability and impact on daily life were found to be relatively low. Only half of the participants believed that pain would disappear after delivery.
- Multivariate analysis showed that women with higher BMI, POP symptoms and more highly educated husbands were significantly more likely to have pregnancy-related PGP and/or LBP.
- Implementing a PFMT program was found to be feasible in pregnant Nepalese women. Fifty-seven percent of the pregnant women attended at least four PFMT visits. Fifty percent of these women reported 50–100% adherence to their daily home PFMT. Women were motivated to perform PFMT, particularly to prevent POP.

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APPENDIX 1

पलैटिकसी बसेर गर्ने

अधेस लिएर गर्ने

सुतेर गर्ने

ध्यान दिनुपर्ने कुराहरू

भारि समान उचाल्नु अघि पाठेघर थेग्ने
मांसपेशी बेस्करी कसेर माथि तान्ने र
१० सेकेन्डसम्म तानिराख्ने ।

दिसा गर्दा नकन्ने

कामको विद्यमा आराम गर्ने ।

**गर्भावस्थामा
पाठेघर थेग्ने
मांसपेशीको व्यायाम**

Pelvic Floor Muscle Exercise
during Pregnancy

गर्भवती अवस्थामा महिलाहरूमा धेरै शारीरिक परिवर्तनहरू आउँछन् । जसका कारण महिलाहरूमा दीर्घकालिन समस्याहरू जस्तै आङ खस्ने र पिसाब चुहिने समस्या देखिन्छ ।

आङ खस्ने र पिसाब चुहिने समस्याले गर्दा महिलाहरूमा पिसाब चुहिने, दुर्गन्ध आउने, दुख्ने र असहजता महशुस हुन्छ । यसले गर्दा दैनिक काम र यौन जीवनमा पनि असर गर्दछ ।

पाठेघर थेग्ने मांसपेशीको व्यायाम कसरी गर्ने

- पाठेघर थेग्ने मांसपेशी बेस्करी कसेर माथि तान्ने र १० सेकेन्डसम्म तानिराख्ने ।
- यहि प्रक्रिया १० पटक सम्म दोहो-याउने ।
- त्यसपछि २ मिनेट आराम गर्ने ।

यो व्यायाम विभिन्न आसानहरूमा पनि गर्न सकिन्छ ।

मेच/कुर्शमा बसेर गर्ने

उठेर/उभिएर गर्ने

पिका वा पिका जस्तै बस्तुमा बसेर गर्ने

APPENDIX 2

गर्भावस्थामा पाठेघर थेग्ने मांशपेशीको व्यायाम

डायरी

ID नं

मिति

व्यायाम गर्ने तरिका

- पाठेघर थेग्ने मांसपेशी बेस्करी कसेर माथि तान्ने र १० सेकेन्डसम्म तानिराख्ने ।
- यहि प्रक्रिया १० पटक सम्म दोहोर्‍याउने ।
- त्यसपछि २ मिनेट आराम गर्ने ।

यो व्यायाम दिनमा
३ पटक दोहोर्‍याउने

कृपया यो डायरी दैनिक रूपमा भर्नुहोस् ।

यदि तपाईंले दिनको ३ पटक गर्नु भएको छ भने ✓ चिन्ह कोर्नुहोस्

यदि तपाईंले दिनको ३ पटक भन्दा कम वा गर्नु भएको छैन भने ✗ चिन्ह कोर्नुहोस्

	दिन १	दिन २	दिन ३	दिन ४	दिन ५	दिन ६	दिन ७
हप्ता १							
हप्ता २							
हप्ता ३							
हप्ता ४							
हप्ता ५							
हप्ता ६							
हप्ता ७							
हप्ता ८							
हप्ता ९							

Cross-Cultural Adaptation and Validation of the Nepali Version of the
Pelvic Girdle Questionnaire

Abstract

Objectives: To translate, cross-culturally adapt, and assess reliability and validity of the Pelvic Girdle Questionnaire (PGQ) in pregnant Nepalese women.

Methods: The cross-cultural adaptation process was conducted according to the Guillemin guidelines. Reliability and validity were assessed using cross-sectional design. The participants responded to questionnaires of sociodemographics, the Nepali version of the PGQ, the Oswestry Disability Index (ODI), the Patient Specific Functional Scale (PSFS), the 5-item version of the Edinburgh Depression Scale (EDS-5), and the Numerical Pain Rating Scale (NPRS). The internal consistency was assessed with Cronbach's alpha. The test-retest reliability was calculated using intraclass correlation coefficient and smallest detectable change. Construct validity was assessed by testing nine a-priori hypothesis that examine correlations between the PGQ activity and symptom subscales, and also between the PGQ subscales and ODI, NPRS, PSFS and EDS-5. Spearman and Pearson's correlation were used to assess the correlations.

Results: A sample of 111 pregnant women were included in the study. The Cronbach's alpha for the Nepali version of the total PGQ was good ($\alpha = 0.83$) and the test-retest reliability was acceptable ($ICC_{2,1}$, 0.72) with the measurement error of $SDC_{95\%}$ 18.6 points. Seven of the nine hypotheses found support, which confirms acceptable construct validity of the Nepali PGQ.

Conclusions: The Nepali version of the PGQ is a reliable and valid tool for assessing pelvic girdle pain in pregnant Nepalese women.

Key-words: cross-cultural adaptation, women's health, pregnancy, pelvic girdle pain, pelvic pain, low back pain, , outcome measure, psychometric properties, reliability, validity, Nepal.

Introduction

Musculoskeletal complaints among pregnant women such as low back pain (LBP) and pelvic girdle pain (PGP) have rarely been studied in Nepal, though back pain is one of the primary complications of pregnancy reported in Nepalese women.¹ Worldwide, the prevalence of pregnancy-related PGP is 20% and 3-10% suffer from persistent PGP.²⁻⁴ Although, PGP and LBP is similar with overlapping features, it should be differentiated.^{5,6} LBP is defined as pain between the twelfth rib and the gluteal fold, whereas PGP refers to pain near the sacroiliac joints between the posterior iliac crest and gluteal fold, and/or in the symphysis pubis.⁵ PGP reduces women's quality of life, ability to work or to carry out day to day activities and negatively influences their sleep.^{2,7-9}

In Nepal, pregnant women perform both agricultural and household work that demands tedious, manual, and intensive labor.^{10,11} Possibly, these women are exposed to commonly reported risk factors of uncomfortable working conditions, frequent lifting, twisting or bending of the body and

a physical strenuous workload.^{5,12-14} It is not known to what extent Nepalese women suffer from PGP, or to what level PGP influences their daily activities and health-related quality of life.

The only condition-specific, reliable, valid and responsive tool for evaluating PGP, the pelvic girdle questionnaire (PGQ) is recommended as a primary instrument for studies on LBP and PGP during pregnancy.¹⁵⁻¹⁸ The PGQ assesses activity limitations and symptoms in women with PGP. As languages are highly associated with cultures, it is important to cross-culturally adapt and test the psychometric properties of an outcome measure.¹⁹ In addition to the original versions in Norwegian and English, the PGQ has to date been translated and validated into Spanish, French-Canadian and Brazilian languages.^{15,20-23} In Nepal, a reliable and valid self-report tool for patients is necessary for examining PGP in clinical practice and for comparing results with international research. The aims of this study were to translate, cross-culturally adapt and test its reliability and validity in pregnant Nepalese women.

Materials and Methods

Design

The study's first part involved translation and cross-cultural adaptation, while the second part comprised a cross-sectional study investigating reliability and validity of the Nepali PGQ.

Ethical approval was obtained from the XXX Regional Ethics Committee (XXX, 2015/2209), The XXX Health Research Council (112/2016), The Institutional Review Committee at XXX and XXX Hospital (25/16).

Procedure of translation and cross-cultural adaptation

The PGQ was translated and cross-culturally adapted according to the Guillemin guidelines²⁴ including the process of “synthesis”, as recommended by Beaton et al. in the “Guidelines for the process of cross-cultural adaptation of self-report measures”.¹⁹ The, process of synthesis involving translation, synthesis, backward translation, expert committee review and pre-testing adds value of resolving translation differences and help to produce one single consensus-based translation.¹⁹

Our translation process was as follows: First, a professional translator and a physiotherapist, both native Nepali speakers, independently translated the English version of the PGQ into Nepali. Second, the translated versions of the PGQ were compared for inconsistencies by one forward translator and one expert committee to obtain a consensus-based forward translation. Third, the synthesised forward-translated version was back-translated into English by a professional English teacher and a health professional, both bilingual in Nepali and English yet entirely unfamiliar with the PGQ. Fourth, an expert committee, including the forward translator, the backward translator, a Nepali physiotherapist, a nurse and a linguist in Nepali, reviewed the translated versions and focused to achieve semantic, idiomatic, experimental, and conceptual equivalence between the Nepali and the English version. After achieving a consensus-based pre-final version of the Nepali PGQ, it was tested in 30 pregnant women attending antenatal control at XXX. The eligibility criteria was ability to speak and read Nepali language. Women were asked to provide comments regarding comprehensibility, wording, and ambiguity.

Participant and procedure of inclusion

The sample size was determined from the recommended Cosmin guidelines that suggested minimum of 50 and 100 participants to study reliability and internal consistency respectively.²⁵ Reliability and validity of the Nepali PGQ were conducted using convenient sampling of pregnant women with PGP attending antenatal control at XXX. Pregnant women attending antenatal control were included in the study if they had pain over the pubic symphysis or sacroiliac joints reproduced by at least one of the following clinical tests; posterior pelvic pain provocation test, active straight leg raise test, pain provocation of the long dorsal sacroiliac ligament and a modified Trendelenburg test.^{5,26} The exclusion criteria were women with psychiatric diagnosis, neuromuscular diseases, unable to understand or communicate in Nepali language and not willing to participate in the study. Written consent was obtained from women fulfilling the criteria.

Two research assistants administered a set of comprehensive questionnaires, which took about 30 minutes to fulfill, and the data were recorded with a Samsung tablet. Test-retest reliability was assessed on the same day by a different assessor following a 5 hours interval.

Measurements

Participants completed a set of questionnaires addressing sociodemographic, pain location on a body chart, the Nepali version of the PGQ, the Oswestry Disability Index (ODI) version 2, the Numerical Pain Rating Scale (NPRS), the Patient-Specific Functional Scale (PSFS), and the 5-item version of the Edinburgh Depression Scale (EDS-5).²⁷⁻³⁰ The original PGQ has shown good psychometric properties such as reliability, construct validity and responsiveness when used in pregnant women.¹⁵⁻¹⁷ It has 25 items with scores from 0-3 and is expressed in percentage scores

from 0-100 (100 = worst possible score).¹⁵ The Nepali version of the PGQ was used to assess the reliability and validity of Nepali PGQ.

In order to compare the construct validity of the Nepali PGQ a set of other measurements were included. First, the commonly used Oswestry Disability Index (ODI) was used as another measure of disability in low back pain.²⁷ The ODI consists of 10 items with scores from 0 -5 and the higher score represents a greater extent of disability. The PSFS was used to assess functional status.²⁸ PSFS was assessed by asking the women to identify up to five activities they have problems completing or cannot complete because of their PGP. Participants rated their ability to complete the activity in a scale from 0 (unable to perform activity) - 10 (able to perform activity). The activity with the lowest score on the PSFS were analyzed in our study. Pain intensity was assessed on a Numerical Pain Rating Scale (NPRS).³⁰ The NPRS consists of 11-point numeric scale that ranges from 0 (no pain) - 10 (worst imaginable pain). The worst pain score on the NPRS were analyzed in our study. The EDS-5 a short version, assesses depressive symptoms and is highly correlated with the Edinburgh Postnatal Depression Scale full version.^{29,31} The total score of the EDS-5 ranges from 0 - 15, where ≥ 8 shows high level of symptoms and ≥ 7 moderate level of symptoms. Nepalese versions of ODI³², NPRS,³³ and PSFS³⁴ were used in the study.

Statistical Analysis

Descriptive data were presented as mean (standard deviation) if normally distributed, as median (minimum-maximum) if skewed, and as frequencies if categorical. Internal consistency was assessed with Cronbach alpha's and interpreted as low if < 0.7 , moderate if 0.7-0.8 and good if $>$

0.8.³⁵ Test-retest reliability was calculated using the intraclass correlation coefficient (ICC_{2.1}) using 2-way random-effects model^{36,37} and an ICC_{2.1} of 0.70 was considered acceptable.³⁵ Paired sample t-tests assessed the differences between test-retest scores. The standard error of measurement (SEM) was calculated as $SD_{diff}/\sqrt{2}$. The SEM was used to calculate the smallest detectable change ($SDC_{95\%} = SEM \times 1.96 \times \sqrt{2}$)³⁵ indicating a real change beyond measurement error with 95% certainty.

Based on the original development of the PGQ we assessed the construct validity by testing nine a-priori hypothesis.¹⁶ The hypotheses are given in Table 4. We expected, however, a lower correlation compared to the original study, as the participants in our study were women visiting the hospital for antenatal control and not patients seeking treatment for PGP. A correlation of < 0.3 was considered low, 0.3-0.6 as moderate, and > 0.6 as high.³⁸ Spearman and Pearson's correlation were used to assess the associations. Seven of nine hypotheses (>75%) has to be confirmed for acceptable construct validity.³⁵

The convergent construct validity was evaluated by assessing the correlations between the PGQ activity and symptom subscales and between the PGQ subscales and the ODI and the NPRS. A high correlation was reported between the PGQ activity and symptom subscales by Grotle et al, thus we expected this correlation to be moderate to high in our sample.¹⁶ We also expected a moderate to high correlation between the PGQ subscales and ODI, as ODI comprised questions of activity and symptoms similar to the PGQ subscales. In line with the study by Grotle et al, who found a moderate correlation between pain and the PGQ subscales,¹⁶ we expected the

correlation between NPRS and the PGQ to be moderate to high for the symptom subscale (which includes a pain domain) and moderate for the activity subscale. Since, PSFS measures activity, we expected the correlation between PSFS and the PGQ activity subscale to be moderate to high while the correlation with the PGQ symptom subscale was expected to be moderate.²⁸

The divergent construct validity was assessed by correlating the PGQ subscales and EDS-5, as mental health measures different constructs compared to the subscales. A low correlation between mental health and the PGQ subscales has previously been reported,¹⁶ thus, we expected the same in this sample.

Floor- and ceiling effects of the Nepali PGQ was assessed by analyzing the percentages of respondents who achieved the lowest (0%) or highest (100%) possible scores. If more than 15% of respondents achieved the lowest or highest possible score, respectively, it was considered floor- or ceiling effect.³⁵ Statistical Package for the Social Sciences version 22.0 was used for analysis.

Results

Translation and cross-cultural adaptation

The committee addressed several cross-cultural adaptations in the pre-final version of the Nepali PGQ. The items 9 "climb stairs", 14 "push a shopping cart", and 15 "run" either lack clarity or applicability in the daily lifestyle of Nepalese culture. First, for item 9 the committee agreed to

reword into "climb upstairs and climb downstairs". The word "climb stairs" in Nepali language does not precisely define climbing upstairs-downstairs. Second, most Nepalese lack access to shopping malls/department stores, so item 14 was modified to "push an object with hand". Third, since running is not a usual activity in Nepalese population, item 15 was changed to "walk fast". Item 16 "carry out sporting activities" and item 19 "have a normal sex life", was expected to have less respondents, as most Nepalese do not regularly engage in sports and due to conservative cultural background participants might resist to answer about sex life.³⁹ Nevertheless, the committee decided to retain both items in the Nepali PGQ as the questionnaire contains 'not applicable' as an option for these two items. No major changes were made after the pilot testing of the pre-final version of Nepali PGQ. The women did not have major comments when filling in the pre-final version of the Nepali PGQ. Only minor changes like spelling corrections were made by the researcher. The final Nepali PGQ version is presented in Appendix 1.

Measurement properties of the Nepali version of the PGQ

Table 1 presents the characteristics of 111 pregnant women included in the study. As expected, only a few participants answered item 16 "carry out sporting activities" and 19 "have a normal sex life" of the Nepali PGQ (Table 2). No missing data were found for the the NPRS, PSFS and the EDS-5.

The internal consistency of the Nepali total PGQ was good ($\alpha=0.83$) whereas the activity subscale ($\alpha=0.72$) and symptom subscale ($\alpha=0.67$) values were found to be lower (Table 2).

The ICC_{2,1} values were acceptable for the Nepali total PGQ (0.72) and the symptoms subscale (0.71). The Nepali total PGQ score showed the least measurement error (SDC_{95%} 18.6 points) whereas symptom subscale scored the largest (SDC_{95%} 25.5 points) (Table 3).

Seven of the nine hypotheses (75%) were supported, indicating an acceptable construct validity for the Nepali PGQ (Table 4). Our result showed no floor- and ceiling effects for the Nepali PGQ as only 1 (0.9%) participant scored 0 and none had a score of 100 on the Nepali PGQ.

Discussion

The aims of the present study were to translate, cross-culturally adapt and assess the reliability and validity of the Nepali PGQ. The Nepali PGQ showed acceptable internal consistency, construct validity, and test-retest reliability. However, large measurement error did emerge. Previously the Spanish PGQ, the French-Canadian PGQ and the Brazilian PGQ have shown adequate and high internal consistency, high test-retest reliability and, construct validity,²⁰⁻²² and the French-Canadian PGQ were also found to be responsive.²¹

In the cross-cultural adaptation process, some modifications were necessary to ensure the PGQ's applicability to Nepali culture but most expressions and meanings of the Nepali version were equivalent to the original PGQ.¹⁵ The items "climb stairs", "push a shopping cart", and "run" were modified in our study. The results of few respondents on items 16 and 19 met our expectations

based upon the adaptation process. However, with the options of "not applicable" for these questions in the PGQ, their lack of response did not affect the measurement properties of the Nepali PGQ.

The internal consistency of Nepali total PGQ was acceptable. Our results corresponded to Grotle et al.¹⁶ whereas the Spanish version showed higher internal consistency, which was speculated to be due to redundancy among the items.²⁰ The Cronbach alpha value for the Nepali total PGQ and PGQ activity subscale showed that items were unidimensional, but not overlapping.³⁵ The PGQ symptom subscale scored lower, which is similar to the findings of Girard et al.²¹ A lower score on the symptom subscale was not surprising given the limited number of items.

The ICC of the Nepali total PGQ was acceptable, although it was lower compared to previous studies.^{16,20,21,22} The symptom subscale of the Nepali PGQ showed a relatively large measurement error despite the short test-retest time interval. We performed a test-retest on the same day with almost 5 hours interval. However during this time period, participants received consultations from gynecologists and midwives and laboratory investigations, which were time-consuming. Hence, the participants might have become fatigued, which could have led to more pain and symptoms at the retest time point. The short test-retest time interval was necessary as many of the women lived far away, and this was the only way to let them answer twice with some time in between. Therefore the test-retest period in our study is shorter as compared to previous studies, which used 7-10 days interval.^{16,20,21,22} The test-retest conducted at different time intervals has not shown any significant differences related to timing of testing.⁴⁰⁻⁴³ The typical duration for antenatal follow-up at the study

site is once in a month. For the test-retest a 30-days interval would have affected the stability of the condition, especially since the participants were pregnant. Moreover the large measurement error could have been influenced by the two assessors who interviewed the participants although the two assessors interviewed in a standardized way.

The Nepali PGQ achieved acceptable construct validity. The correlation between the PGQ subscales and the PSFS was, however, less than expected. A possible explanation could be that the women were actively involved in work despite suffering from pain.⁴⁴ Consistent with previous validity studies on PGQ, our study also presented no floor and ceiling effects on the Nepali PGQ.²⁰⁻²²

For the feasibility of our study we included only pregnant women. Most women visit XXX for antenatal control and, as many do not deliver at the hospital, it would be a great challenge to recruit post-natal women. Furthermore, women visiting the hospital come from far-off distances and there is no appointment system for visits by the gynecologists. Previous PGQ validity studies have included both pregnant and postpartum women and used postal surveys and e-platforms for data collection,^{16,20,21} except for the Brazilian PGQ that included pregnant women.²² In a country like XXX, it would have been impossible to collect data using postal surveys or e-platforms due to the lack of infrastructure and low education rate.

However, we do not know if inclusion of post-partum women would have made significant differences in our results. The study by Grotle et al,¹⁶ showed no differences in the PGQ construct validity and reliability between the pregnant and postpartum women, except for the differences in discriminant validity of the PGQ. Still, the lack of postpartum women remains a limitation of our study.

Women involved in the pre-final testing of the Nepali PGQ were also included in the validity and reliability study of Nepali PGQ. It has been recommended to include pilot data to increase the efficiency of the main study.⁴⁵

In our study, the research assistants read aloud the questions to the participants and their answers were documented in an electronic device (Samsung Tablet), whereas in previous studies the participants themselves filled in the PGQ.^{15,16,20} The difference in the data collection procedure could have influenced the results. However, a recent review reported no evidence of bias in self-completed versus assisted modes of administration in patient-reported outcomes.⁴⁶ Most women who attended XXX came from rural areas, and most of them lack the ability to complete the questionnaires independently.

Strengths and limitations

The translation and cross-cultural adaptation process of the PGQ questionnaire was conducted using a recommended cross-cultural adaptation guidelines.^{19,24} Furthermore, the inclusion of participants with clinically confirmed PGP is one of the major strengths of our study. Another

strength is the sample size of 111 women, which is according to the recommendations for investigating methodological quality in outcome measures.²⁵

Possible limitation is the short time interval for test-retest. However, no significant differences have reported for test-retest done in different time intervals.⁴³ But our failure to ask whether the women's conditions had changed between the test-retest constitutes a limitation to our study. Given the expected short interval in our study between the test-retest, the probability of remembering the women's answers was high so a different assessor performed the retest to avoid bias. Regardless, use of different assessors is still a limitation of our study. Another limitation could be the oral administration of questionnaires by research assistants to the participants though no evidence of bias was reported with different modes of questionnaire administration.⁴⁶ Moreover, our results found that majority of our participants had lower educational level which could have led to the limitation of completing the questionnaires independently. Thus, the oral administration of the questionnaire may have strengthened the validity of our study.

Conclusion

The Nepali version of the PGQ displayed acceptable internal consistency, test-retest reliability, and construct validity. The measurement error for the PGQ symptom subscale was large, however. The Nepali PGQ is considered to be a useful as a tool for pregnant Nepalese women with PGP in clinical settings and for research purposes.

Conflict of interest: None

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450 **Table 1. Characteristics of the study participants (n=111)**

Variables	Value
Age (years), mean (SD)	25 (4)
Weeks of gestation, mean (SD)	25 (10)
Body mass index (kg/m ²), mean (SD)	26 (4)
Number of pregnancies, n (%)	
1	58 (52)
2	40 (36)
3	7 (6)
4	5 (5)
5	1 (1)
Educational level, n%*	
Primary	7 (6)
Secondary	38 (34)
Higher secondary	37 (33)
Bachelor	23 (21)
No education	6 (5)
Independent income, n (%) *	
Yes	24 (21)
No	86 (77)
Pain location, n (%)	
Right sacroiliac joint	82 (73)

Validation of Nepali Pelvic Girdle Questionnaire

Left sacroiliac joint	78 (70)
Sacrum	86 (77)
Symphysis pubis	29 (26)
NPRS, mean (SD)	5 (2)
PSFS, mean (SD)	3 (1)
Nepali PGQ	
Total score, mean (SD)	33 (14)
Activity subscale, mean (SD)	34 (14)
Symptom subscale, mean (SD)	29 (18)
ODI, median (IQR)	36 (18)
EDS-5, median (IQR)	2 (5)
SD: Standard deviation, IQR: Interquartile range, NPRS: Numerical Pain Rating Scale (0=no pain, 10=worst pain), PSFS: Patient Specific Functional Scale ((0=unable to perform activity, 10=able to perform activity), PGQ: Pelvic Girdle Questionnaire (0=no problem at all, 100= to a large extent); ODI: Oswestry Disability Index (0=no disability, 100=maximum disability), EDS-5:Edinburgh depression scale-5(0= no depression symptom, 15= high depression symptom)	
*Missing =1	

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457 **Table 2. Missing Data and Internal Consistency for the Nepali Pelvic Girdle Questionnaire**

Nepali PGQ items	Missing value (n)	Mean	SD	Cronbach Alpha/ Item- Total correlation
Total PGQ				0.83
Activity subscale				0.72
1. Dress yourself	0	0.13	0.38	0.27
2. Stand for less than 10 minutes	0	0.34	0.51	0.27
3. Stand for more than 60 minutes	0	1.65	0.94	0.45
4. Bend down	0	1.71	1.01	0.46
5. Sit for less than 10 minutes	0	0.29	0.49	0.18
6. Sit for more than 60 minutes	0	1.50	0.93	0.53
7. Walk for less than 10 minutes	0	0.30	0.55	0.32
8. Walk for more than 60 minutes	0	1.64	0.87	0.45
9. Climb up and down the stairs	0	0.81	0.84	0.41
10. Do housework	0	0.96	0.8	0.44
11. Carry light objects	0	0.21	0.41	0.36

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12. Carry heavy objects	0	1.44	1.03	0.49
13. Get up/sit down	0	1.20	0.97	0.40
14. Push object with hand	0	0.43	0.68	0.38
15. Walk fast	0	1.62	1.15	0.61
16. Carry out sporting activities	110	0	0	0
17. Lie down	0	1.54	1.04	0.29
18. Roll over in bed	0	1.9	1.08	0.46
19. Have a normal sex life	35	1.63	1.93	0.15
20. Push something with one foot	0	0.34	0.58	0.48
Symptom subscale				0.67
21. Pain in the morning	0	0.8	0.88	0.29
22. Pain in the evening	0	1.43	0.84	0.52
23. Has your leg/have your legs given way?	0	0.86	0.84	0.40
24. Do you do things more slowly?	0	0.68	0.65	0.65
25. Is your sleep interrupted?	0	0.51	0.75	0.46
SD: standard deviation, PGQ: Pelvic Girdle Questionnaire				

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Table 3. Test-Retest Scores, Measurement Error, and Intraclass Correlation Coefficient of the Nepali Pelvic Girdle Questionnaire (n=111)

Nepali PGQ	Test score Mean, SD	Re-test score Mean, SD	Mean difference, SD,CI	SEM	SDC _{95%}	ICC (95% CI)
Total	32.9 (13.6)	36.7 (13.3)	3.8 (9.5) (-5.57- -1.99)	6.7	18.6	0.72 (0.58-0.81)
Activity subscale	34.1 (14.1)	39.3 (14.2)	5.2 (10.5) (-7.15- -3.21)	7.4	20.5	0.68 (0.49-0.80)
Symptom subscale	28.6 (17.5)	27.3 (17.0)	1.4 (13.1) (-0.18 – 3.84)	9.2	25.5	0.71 (0.61-0.80)
SD: standard deviation, SEM: standard error measurement, SDC: smallest detectable change, CI:confidence interval, ICC: intraclass correlation coefficient, PGQ: Pelvic Girdle Questionnaire						

Table 4. Construct validity of the Nepali Pelvic Girdle Questionnaire (n = 111)

Hypothesis	Spearman correlation	Pearson Correlation	Hypothesis confirmed?
Moderate-high correlation between PGQ activity subscale and PGQ symptom subscale		0.56 (< 0.001)	YES
Moderate-high correlation between PGQ activity subscale and ODI	0.48 (< 0.001)		YES
Moderate-high correlation between PGQ symptom subscale and ODI	0.42 (< 0.001)		YES
Moderate correlation between PGQ activity subscale and NPRS	0.39 (< 0.001)		YES
Moderate-high correlation between	0.51 (< 0.001)		YES

Validation of Nepali Pelvic Girdle Questionnaire

PGQ symptom subscale and NPRS			
Moderate-high correlation between PGQ activity subscale and PSFS		-0.11 (0.235)	NO
Moderate correlation between PGQ symptom subscale and PSFS		-0.28 (< 0.002)	NO
Low correlation between PGQ activity subscale and EDS	-0.16 (0.083)		YES
Low correlation between PGQ symptom subscale and EDS	0.16 (0.094)		YES
PGQ: Pelvic Girdle Questionnaire, ODI: Oswestry Disability Index, NPRS: Numerical Pain Rating scale, PSFS: Patient Specific Functional Scale, EDS-5: Edinburgh Depression Scale-5 items			

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RESEARCH ARTICLE

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Prevalence and severity of low back- and pelvic girdle pain in pregnant Nepalese women

Ranjeeta Shijagurumayum Acharya^{1,2,3*} , Anne Therese Tveter^{4,5}, Margreth Grotle^{4,6}, Malin Eberhard-Gran^{2,7,8} and Britt Stuge³

Abstract

Background: Low back pain (LBP) and pelvic girdle pain (PGP) are commonly reported during pregnancy and are known to affect pregnant women's well-being. Still, these conditions are often considered to be a normal part of pregnancy. This study assesses the prevalence and severity of LBP and/or PGP among pregnant Nepalese women, as well as exploring factors associated with LBP and PGP.

Methods: A cross-sectional study with successive recruitment of pregnant women was conducted at two district hospitals in Nepal from May 2016 to May 2017. The data was collected using self-reported questionnaires. Univariate and multivariate logistic regression were used to assess the associations between independent variables and LBP and/or PGP.

Results: A total of 1284 pregnant women were included in the study. The reported prevalence of pregnancy-related LBP and/or PGP was 34%. Pain intensity was high with a mean score (standard deviation) of 6 (2). The median (25th–75th percentiles) disability scores according to the total Pelvic Girdle Questionnaire and Oswestry Disability Index were 20 (10–32) and 30 (21–38), respectively. Even though only 52% of the women believed that the pain would disappear after delivery, concern about LBP and/or PGP was reported to be low (median 2 (0–4) (Numeric Rating Scale 0–10)). In the final model for women with LBP and/or PGP the adjusted odds ratios were for body mass index (20–24, 25–30, > 30) 0.7 (95% confidence interval (CI), 0.44–1.21), 1.1 (95% CI, 0.66–1.83), and 1.5 (95% CI, 0.78–2.94) respectively, for pelvic organ prolapse symptoms 6.6 (95% CI, 4.93–8.95) and for women with educated husbands (primary or secondary, higher secondary or above) 1.1 (95% CI, 0.53–2.16) and 1.7 (95% CI, 0.84–3.47), respectively.

Conclusions: Pregnant Nepalese women commonly report LBP and/or PGP. The women experienced low disability despite severe pain intensity and poor beliefs in recovery after delivery.

Keywords: Pelvic girdle pain, Low back pain, Pelvic pain, Women's health, Nepal, Pregnancy, Prevalence, Severity, Function, Impact

* Correspondence: ranjeetashija@gmail.com

¹Department of Physiotherapy, Kathmandu University School of Medical Sciences, Kathmandu University Dhulikhel Hospital, Kavre, Nepal

²Institute of Clinical Medicine, University of Oslo, Oslo, Norway

Full list of author information is available at the end of the article

Introduction

Global progress in maternal mortality rate reduction has placed emphasis on maternal morbidity, addressing maternal well-being and mental health [1, 2]. The World Health Organization's Maternal Morbidity Working Group defined maternal morbidity as "any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman's wellbeing" [2].

As the most common pregnancy-related musculoskeletal problems that impact pregnant women's well-being are low back pain (LBP) and pelvic girdle pain (PGP), these conditions have garnered increasing interest worldwide [3–6]. LBP is defined as pain between the twelfth rib and the gluteal fold, while PGP is defined as pain experienced between the sacroiliac joint and the gluteal fold, or in the symphysis pubis [7]. The prevalence of pregnancy-related LBP and PGP varies from 20 to 80%, with the majority of studies reporting approximately 50% for LBP and/or PGP, and 20% for PGP specifically [4, 6–10].

Though not life-threatening conditions, pregnancy-related LBP and PGP may affect daily activities such as walking, working, sleep, and mood, thereby reducing quality of life [4, 5]. Commonly reported risk factors for pregnancy-related LBP and PGP are strenuous workload, frequent or prolonged torso flexion, previous history of LBP or PGP, and previous trauma to the pelvis [7, 8, 11]. Body mass index (BMI), parity, and depression are also found to be associated with LBP and PGP [6, 9, 10].

Nepal's main source of income is agriculture, with 76% of households involved in agricultural activities, and 84% of women involved in agricultural work [12, 13]. The increase in labor migration among Nepal's men has led to a triple role for women, who are involved in reproduction, agricultural production, and household work [14, 15]. The number of Nepalese women faced with physically strenuous work, little time for rest, and reduced family support, even during pregnancy, is high [16].

Pregnancy-related LBP and PGP are not generally regarded as serious complications and can thus be overlooked by healthcare professionals [4]. Nevertheless, disability and negative psychological effects related to LBP and PGP have been reported in many countries [4–6, 9, 10, 17–19]. A lack of awareness of the impairment caused by these musculoskeletal complaints can result in poor management of pregnant women. A multinational study showed variation in the prevalence, severity, and concern surrounding pregnancy-related LBP and PGP across different countries [4]. Societal attitudes, ethnicity, and cultural beliefs might influence how pregnancy-related LBP and/or PGP are perceived [20, 21]. Most studies on pregnancy-related LBP and PGP have been

conducted in developed countries, and it seems that these conditions are often overlooked in developing countries [22].

To our knowledge, the prevalence and severity of pregnancy-related LBP and PGP have never been examined in Nepal [23]. Thus, the primary aim of this study was to assess the prevalence and severity of LBP and PGP in pregnant Nepalese women. A secondary aim was to determine the factors that influence LBP and PGP during pregnancy.

Methods

Study design and setting

A cross-sectional study with successive recruitment of pregnant women was conducted at two district hospitals in Nepal from May 2016 to May 2017. KIST Teaching Hospital in Lalitpur district is situated in the capital city Kathmandu, whereas Kathmandu University Dhulikhel Hospital (KUDH), in Kavreplanchowk district, is located 30 km northeast from Kathmandu. KIST and KUDH hospitals see about 1200 and 3500 live births each year, respectively.

Participants

Pregnant women attending antenatal control at KUDH and KIST hospitals were eligible for inclusion in the study if they were willing to participate, had no history of spinal fracture or surgery, and could understand and speak Nepali. Oral and written consent was obtained from women who agreed to participate in the study. One of two research assistants collected and recorded data on a Samsung tablet with open data kit software.

Ethical approval was obtained from the Norwegian Regional Ethics Committee (REK Nord, 2015/2209), the Nepal Health Research Council Ethical Review Board (112/2016), and the Institutional Review Committee of Kathmandu University School of Medical Sciences/Dhulikhel Hospital (25/16).

Measurements

Participants completed questionnaires on sociodemographic, pregnancy, and workload characteristics. Sociodemographic information included: age (years), height (cm), weight (kg), ethnicity, women's and husbands education in years (no education, primary ≤ 5 , lower secondary 6–8, secondary 9–10, higher secondary 11–12, bachelor and above ≥ 13), monthly income in United States dollars (USD,\$) (no income, less than \$76, \$76–153, $> \$153$), occupation, marital status (living with husband, husband working away from home, divorced), type of family (nuclear: husband and children; joint: parents-in-law, husband, and children; extended: grandparents, parents-in-law, husband, and children), number of family members, and household work (washing/cleaning/

cooking, child care, animal care, fetching water). Pregnancy characteristics included number of pregnancies, parity, and gestation (weeks). Workload information included waking hours, hours of rest during work, types of field work (farming, grass cutting, branch cutting, fetching water), working positions (sitting or squatting, standing or bending forward), and hours of prolonged sitting or standing.

The registration of LBP and PGP was done using a body chart. Participants who reported musculoskeletal pain were asked to indicate the location of their pain on a body chart, which was then validated by having the women point to the site of the pain on their body. If the women pointed to their lower back and/or pelvis, they were considered to have LBP and/or PGP. A physiotherapist then performed further clinical examination on women reporting LBP and/or PGP [7, 24, 25].

The women who reported LBP and/or PGP also responded to questions regarding pain intensity (numeric rating scale, 0 (no pain) to 10 (the most severe pain)) [26, 27], pain frequency (on some days, most days, every day), specific pelvic pain locations (sacrum, sacroiliac joints, and symphysis pubis), whether the LBP and/or PGP limited their usual activities or changed their daily routine for more than 1 day (no/yes) [28], whether they were concerned about the LBP and/or PGP (numeric rating scale, 0 (not concerned) to 10 (extremely concerned)), and whether they believed that the LBP and/or PGP would disappear after delivery (no/yes).

Reliable and valid Nepalese versions of outcome measures were used to assess the severity of activity limitations and symptoms of pregnancy-related LBP and PGP. The Oswestry Disability Index (ODI), version 2 [29, 30], consists of 10 items with scores from 0 to 5, describing an increasing degree of difficulty. The Pelvic Girdle Questionnaire (PGQ) comprises 25 items with scores on a 4-point descriptive scale from 0 to 3, describing an increasing degree of symptoms and activity limitations [31–33]. The total sum score for both the ODI and the PGQ is expressed as a percentage from 0 to 100 (severe disability).

The women completed questionnaires on pelvic organ prolapse (POP) symptoms, urinary incontinence (UI), and depression symptoms. The POP symptom score (POP-SS) ranges from 0 to 28, with higher scores indicating more severe symptoms [34]. The International Consultation on Incontinence Questionnaire-UI Short Form (ICIQ-UI SF) score ranges from 0 to 21, with higher scores representing more severe UI symptoms [35]. The short five-item version of the Edinburgh Depression Scale (EDS-5) has four alternative answers to each question, scored from 0 to 3, adding up to a maximum score of 15 to represent the highest severity of depression [36].

Statistical analysis

Continuous variables with normal distribution are presented as mean (standard deviation (SD)) or median (interquartile range (iqr), 25th and 75th percentiles) if skewed. Categorical data are presented as numbers and percentages.

To assess the associations between independent variables and LBP and/or PGP, univariate and multivariate logistic regression with odds ratios (OR) and 95% confidence intervals (CIs) were used. The authors planned to include 20 independent variables to assess these associations, requiring at least 200 participants with pregnancy-related LBP and/or PGP. Prior to logistic regression analysis, the independent variables were tested for collinearity, and correlations greater than 0.7 were considered to be one-dimensional. Following this rule, potential univariate associations for 20 independent variables with the outcome of LBP and/or PGP were analyzed using Mann-Whitney U or Chi-square tests, depending on whether variables were continuous or categorical. Variables with *p*-values less than or equal to 0.25 were included in the multivariate regression model.

In order to enhance interpretability, the variables are presented in the following categories: age: ≤ 21 , 22–24, 25–27, ≥ 28 years; weeks of gestation: 1–12, 13–28, 29–40; BMI: < 20 , 20–24, 25–30, > 30 ; education: no education, primary-secondary (5–10 years), higher secondary and above (≥ 11 years); monthly income: no income, $\leq \$153$, and $> \$153$; child care (no/yes), fetching water (no/yes), field work (no/yes), rest during work (no/yes); POP-SS: no symptoms vs ≥ 3 symptoms of POP (75th percentile); ICIQ-UI SF: no UI or reported UI; and EDS-5: < 5 or ≥ 5 symptoms of depression. A backward strategy was used in the multivariate modelling. Variables with *p*-values greater than or equal to 0.05 were excluded. Variables in the final model were checked for pair-wise interactions. The Statistical Package for the Social Sciences (SPSS) version 22 was used for statistical analysis.

Results

A total of 1284 pregnant women (54% from KUDH and 46% from KIST) were included in the study (Table 1). The mean age of the participants was 25 (SD 4) years, with a mean of 24 (SD 10) gestation weeks. Fifty-eight percent of the women were nulliparous. More than half of the women had secondary education, but only 14% had a monthly income. Fifty-two percent of the participants had to take care of animals and fetch water in addition to doing usual household work. Only one-third of the women reported taking breaks to rest while working, and the reported mean hours of rest per day was 1 (SD 1). Fifteen percent ($n = 195$) of the participants were involved in field work. Farming and grass cutting were

Table 1 Characteristics of pregnant women included in the study ($n = 1284$)

Variables	Value
Age, years, mean (SD)	25 (4)
Gestational week, mean (SD) ^a	24 (10)
Number of pregnancies, median (iqr)	2 (1–2)
Parity, n (%)	
0	751 (58)
1	461 (36)
≥ 2	72 (6)
Body mass index, kg/m ² , mean (SD) ^b	25 (4)
Marital status, n (%)	
Living with husband	1161 (90)
Husband works away from home	121 (10)
Divorce	2 (0)
Husband residing abroad, n (%)	85 (7)
Type of family, n (%)	
Nuclear (husband and children)	593 (46)
Joint (parents-in-law, husband, and children)	645 (50)
Extended (grandparents, parents-in-law, husband, and children)	46 (4)
Number of family members, mean (SD)	5 (3)
Ethnicity, n (%)	
Brahmin	244 (19)
Chhetri	231 (18)
Newar	283 (22)
Tamang	267 (21)
Magar	54 (4)
Dalit	74 (6)
Others	131 (10)
Participant's education, years, n (%)	
No education	113 (9)
Primary (≤ 5)	148 (11)
Lower secondary (6–8)	174 (13)
Secondary (9–10)	303 (24)
Higher secondary (11–12)	341 (27)
Bachelor and above (≥ 13)	205 (16)
Husbands education, years, n (%)	
No education	60 (5)
Primary (≤ 5)	131 (10)
Lower secondary (6–8)	195 (15)
Secondary (9–10)	330 (26)
Higher secondary (11–12)	338 (26)
Bachelor and above (≥ 13)	230 (18)
Women with monthly income, USD, n (%)	
No income	1100 (86)
< 76	55 (4)
76–153	72 (6)

Table 1 Characteristics of pregnant women included in the study ($n = 1284$) (Continued)

Variables	Value
> 153	57 (4)
Husband with monthly income, USD, n (%)	
No income	862 (67)
< 76	24 (2)
76–153	150 (12)
> 153	248 (19)
Occupation, n (%)	
Housewife	1160 (90)
Agriculture	54 (4)
Business (owns a shop, cattle rearing etc.)	114 (9)
Employed (government and private)	124 (10)
Others (labor, student)	26 (2)
Household work, n (%)	
Washing, cleaning, cooking	1284 (100)
Child care	451 (35)
Animal care	207 (16)
Fetching water	463 (36)
Field work, n (%)	195 (15)
Waking hours in a day, mean (SD)	15 (2)
Rest taken during work, n (%)	436 (34)
LBP and/or PGP in past 4 weeks, n (%)	432 (34)
POP-SS, median (iqr)	0 (0–3)
ICIQ-UI SF, median (iqr)	0 (0–0)
EDS-5, median (iqr)	2 (0–4)

SD Standard deviation; Interquartile range (iqr; percentiles 25th – 75th), USD United States dollar, LBP Low back pain, PGP Pelvic girdle pain, POP-SS Pelvic organ prolapse symptom score, ICIQ-UI SF International consultation on incontinence questionnaire- urinary incontinence short form, EDS-5 Edinburgh depression scale 5-item version

^amissing number: 15

^bmissing number: 7

the most common types of field work, and most of the women's working hours were spent either sitting, standing, or bending forward, with a mean of 3 (SD 2) hours of prolonged standing.

The reported prevalence of pregnancy-related LBP and/or PGP was 34% (Table 1). The sacrum and sacroiliac joints were the most commonly reported sites of pelvic pain, and only 7% of the women had pain in all three of the pelvic joints (Table 2). The clinical examination was limited, as many of the women refused to perform all clinical tests. The posterior pelvic pain provocation test was, however, performed in 379 (88%) women, and 73% had a positive result. Among the participants reporting LBP and/or PGP, evening pain intensity was reported to be high, with a mean of 6 (SD 2), while the total PGQ and ODI scores showed low and moderate disability, respectively. Twenty-four percent of the women had pain most days, and one-third reported a limitation of their ability to perform their usual

activities for more than 1 day due to LBP and/or PGP. Concern about LBP and/or PGP was reported to be low (median 2 (iqr 0–4)). Almost 50% of the participating women were either unsure or did not believe that their pain would disappear after delivery.

The univariate analyses showed a higher likelihood of pregnancy-related LBP and/or PGP in women with increased BMI, increasing weeks of gestation, higher education and higher monthly income, symptoms of POP, UI and depression, women who fetched water, and those whose husbands had a higher education and a higher monthly income (Table 3). The multivariate regression analysis showed significant associations in women with increased BMI, with husbands with higher education, and for women with POP symptoms (Table 4). No interactions were observed in the multivariate model. The strongest association was found between reported POP symptoms and LBP and/or PGP.

Table 2 Descriptives of self-reported low back pain (LBP) and/or pelvic girdle pain (PGP) ($n = 432$)

Variables	Value
LBP/PGP frequency, n (%)	
Some days	285 (66)
Most days	102 (24)
Every day	45 (10)
Limit daily activities, n (%)	139 (32)
Pelvic pain location, n (%)	
Symphysis pubis	55 (13)
Right sacroiliac joint	262 (61)
Left sacroiliac joint	250 (58)
Sacrum	347 (80)
Pain intensity (NRS 0–10) in past 4 weeks, mean (SD)	5 (2)
Evening pain intensity (NRS 0–10) in past 4 weeks, mean (SD)	6 (2)
Concern about LBP and/or PGP (NRS 0–10), median (iqr)	2 (0–4)
Pain will disappear after delivery, n (%)	
Yes	224 (52)
No	117 (27)
Uncertain	89 (21)
Pelvic Girdle Questionnaire (PGQ), (0–100)	
PGQ total score, median (iqr)	20 (10–32)
PGQ activity subscale score, median (iqr)	21 (9–32)
PGQ symptom subscale score, median (iqr)	20 (7–33)
Oswestry Disability Index (ODI) (0–100), median (iqr)	30 (21–38)

SD Standard deviation; Interquartile range (iqr; percentiles 25th–75th), NRS Numeric rating scale

Discussion

In this one-year prevalence study we found that LBP and/or PGP were commonly reported in pregnant Nepalese women. Though the reported pain intensity was high, disability and impact on daily life was found to be low. Only half of the participants believed that their pain would disappear after delivery. Multivariate analysis showed that women with increased BMI, POP symptoms, and husbands with higher education were significantly more likely to have pregnancy-related LBP and/or PGP.

The prevalence of LBP and/or PGP is consistent with a recent study from Western Nepal, in which back pain was reported as one of the most common complications during pregnancy [23]. A comparable study from another developing country also reported that LBP and PGP were commonly reported during pregnancy [17]. Still, the reported prevalence of pregnancy-related LBP and/or PGP in our study was found to be lower (34%) compared to studies in developed countries (45–86%) [4, 6, 8–10]. Possible explanations for the lower prevalence could be that most of our participants were pregnant for the first time, with a mean gestation of 24 weeks, compared to participants in other studies who were in their third trimester [4, 6, 10]. One or more previous

deliveries and increasing numbers of weeks of gestation have been reported to increase the risk of LBP and/or PGP [9, 10, 17, 37].

Prevalence rates might also be influenced by the way data is collected. Data on LBP and PGP are commonly collected using questionnaires [4, 38]. Optimally, classification of LBP and PGP should be done through a thorough clinical examination [7]. Unfortunately, we were not able to clinically examine all the women. We based our classification on a validated body chart by asking the women to point to the pain on their body site. Body charts have previously been used to determine LBP and/or PGP; however, in contrast to our study, many studies lack a validation of the body chart [4, 10].

Compared to a recent international study, the women in our study showed higher pain intensity than women in the United States, Norway, and Sweden, but lower than women in the United Kingdom [4]. The women in the United Kingdom had lower education than the women studied in the other countries. The majority of the women in our sample also had lower education levels, which could be one reason for their reported high pain intensity, as education level has been found to be associated with severity of symptoms [39].

Table 3 Univariate analysis of factors associated with and without pregnancy-related low back pain (LBP) and/or pelvic girdle pain (PGP)

Variables	With LBP and/or PGP (n = 432)	Without LBP and/or PGP (n = 852)	Odds ratio (95% confidence interval)	P-value
Age, years, n (%)				
≤ 21	92 (21)	238 (28)	–	0.08
22–24	133 (31)	243 (28)	1.4 (1.03–2.00)	
25–27	99 (23)	177 (21)	1.5 (1.03–2.04)	
≥ 28	108 (25)	194 (23)	1.4 (1.03–2.02)	
Weeks of gestation, n (%)				
1–12	52 (12)	127 (15)	–	0.09
13–28	208 (49)	430 (51)	1.2 (0.82–1.70)	
29–40	168 (39)	284 (34)	1.4 (0.99–2.10)	
Body mass index, n (%)				
< 20	36 (10)	63 (9)	–	< 0.001
20–24	142 (38)	371 (50)	0.7 (0.43–1.05)	
25–30	159 (42)	259 (35)	1.1 (0.68–1.69)	
> 30	39 (10)	45 (6)	1.5 (0.84–2.74)	
Participant's education, years, n (%)				
No education	25 (6)	88 (10)	–	0.003
Primary-secondary (5–10)	200 (46)	425 (50)	1.7 (1.03–2.66)	
Higher secondary and above (≥ 11)	207 (48)	339 (40)	2.2 (1.33–3.46)	
Husbands education, years, n (%)				
No education	15 (3)	45 (5)	–	0.004
Primary- secondary (5–10)	199 (46)	457 (54)	1.3 (0.71–2.40)	
Higher secondary and above (≥ 11)	218 (51)	350 (41)	1.9 (1.02–3.43)	
Participant's monthly income, USD, n (%)				
No income	352 (81)	748 (88)	–	0.009
≤ 153	56 (13)	71 (8)	1.7 (1.16–2.43)	
> 153	24 (6)	33 (4)	1.6 (0.90–2.65)	
Husbands monthly income, USD, n (%)				
No income	265 (61)	597 (70)	–	0.007
≤ 153	68 (16)	106 (12)	1.4 (1.03–2.03)	
> 153	99 (23)	149 (18)	1.5 (1.11–2.01)	
Child care, n (%)				
No	291 (67)	542 (64)	–	0.18
Yes	141 (33)	310 (36)	0.8 (0.66–1.08)	
Fetching water, n (%)				
No	260 (60)	561 (66)	–	0.05
Yes	172 (40)	291 (34)	1.3 (1.00–1.62)	
Field work, n (%)				
No	356 (82)	733 (86)	–	0.09
Yes	76 (18)	119 (14)	1.3 (0.96–1.80)	
Rest during work, n (%)				
No	271 (63)	577 (68)	–	0.07
Yes	161 (37)	275 (32)	1.2 (0.98–1.59)	
POP-SS, n (%)				

Table 3 Univariate analysis of factors associated with and without pregnancy-related low back pain (LBP) and/or pelvic girdle pain (PGP) (Continued)

Variables	With LBP and/or PGP (n = 432)	Without LBP and/or PGP (n = 852)	Odds ratio (95% confidence interval)	P-value
0–2 (no symptoms of POP)	209 (48)	731 (86)	–	< 0.001
≥ 3 (symptoms of POP)	223 (52)	121 (14)	6.4 (4.92–8.34)	
ICIQ-UI SF, n (%)				
0- No UI	333 (77)	723 (85)	–	0.003
1- Reported UI	99 (23)	129 (15)	1.7 (1.24–2.23)	
EDS-5, n (%)				
< 5 - no symptoms of depression	309 (72)	714 (84)	–	< 0.001
≥ 5 - symptoms of depression	123 (28)	138 (16)	2.1 (1.56–2.72)	

USD United States dollar, POP-SS Pelvic organ prolapse symptom score, ≥ 3 (symptoms of POP); 75th percentile, ICIQ-UI SF International consultation on incontinence questionnaire-urinary incontinence short form, EDS-5 Edinburgh depression scale 5-item version (cut off ≥ 5 for symptoms of depression)

Despite high pain intensity, low disability scores were observed. Reported disability rates were much higher in pregnant women in Scandinavian countries, the United Kingdom, and the United States [4]. This result could be influenced by the differences in gestational period among the various groups of women studied, nevertheless, the inconsistency between pain intensity and disability is surprising. Only 10% of our sample reported LBP and/or PGP every day, and only one-third of the women reported that they had to limit their daily activities. These rates are lower than those seen in the study by Gutke et al. [4] Pain tolerance has been shown to be strongly associated with ethnic differences [20]. The

differences in impact on daily life might be explained by the way Nepalese women adapt to pain or adopt different ways of coping with pain. Another possible explanation could be the neglect of health problems in Nepal due to the challenges of survival and meeting basic needs [16].

The participants were not very concerned about their LBP and/or PGP, even though only half of them believed that their pain would disappear after delivery. This belief in persistent pain postpartum could be due to lack of knowledge regarding the prognosis and recovery for LBP and PGP after delivery [40]. A study from Nepal reported the challenges faced by healthcare providers in

Table 4 Multivariate analysis of factors associated with pregnancy-related low back pain (LBP) and/or pelvic girdle pain (PGP)

Variables	Odds ratio (95% confidence interval)	P-value
Age, years, n (%)		
≤ 21	–	0.54
22–24	1.3 (0.86–1.85)	
25–27	1.3 (0.84–1.90)	
≥ 28	1.3 (0.87–1.96)	
Body mass index, n (%)		
< 20	–	0.01
20–24	0.7 (0.44–1.21)	
25–30	1.1 (0.66–1.83)	
> 30	1.5 (0.78–2.94)	
Husbands education, years, n (%)		
No education	–	0.003
Primary- secondary (5–10)	1.1 (0.53–2.16)	
Higher secondary and above (≥ 11)	1.7 (0.84–3.47)	
	POP-SS, n (%)	
0–2 (no symptoms of POP)	–	< 0.001
≥ 3 (symptoms of POP)	6.6 (4.93–8.95)	

Adjusted for age in the multivariate analysis

POP-SS Pelvic organ prolapse symptom score, ≥ 3 (symptoms of POP); 75th percentile

providing information to patients with low education [41]. The lower educational level of our sample and lack of information regarding common pregnancy complaints might have led to their belief in persistent LBP and/or PGP postpartum.

We found that women with a higher BMI were more likely to report LBP and/or PGP. This finding is consistent with several previous studies [6, 9, 10, 42], although one study [43] reported no association. One surprising finding in the current study was that women with educated husbands were positively associated with pregnancy-related LBP and/or PGP. The majority of the women in our study were unemployed, and since highly educated husbands probably work away from home, it is likely that these women are responsible for household work, which might result in an increased strenuous physical workload influencing LBP and PGP [8, 11]. Our finding is supported by another study from Nepal where the overburden of physical work on women is reported to be due to the migration of their husbands, either to urban centers or abroad, for employment [15]. Half of the women in our study had to fetch water and take care of animals, in addition to household chores, and 15% of the studied women were also involved in field work. Heavy physical workload might be a reason for Nepalese women reporting a significantly higher prevalence of backache compared to Nepalese men [44].

POP symptoms were also found to be associated with pregnancy-related LBP and/or PGP in our study. LBP, PGP, and POP are reported to be influenced by weakness and laxity of the muscles and their supporting structures [45, 46]. During pregnancy the laxity of pelvic ligaments is exacerbated due to the release of the hormone relaxin [47]. Even though increased concentration of relaxin is seen during pregnancy, a positive association has not been established between pregnancy-related PGP and relaxin [48]. Dufour et al. [49] reported high correlations between pelvic organ dysfunction and lumbo-pelvic pain, whereas Stuge et al. [50] reported no evidence for impaired pelvic floor muscle function in postpartum women with PGP, though a tendency towards POP was reported. We used POP-SS, which is a self-reported outcome measure for identifying POP symptoms, and as one of the questions is related to LBP this might influence the association.

Our univariate model showed significant associations of LBP and/or PGP with women with higher education and income, women whose husbands had higher income, weeks of gestation, workload (fetching water, rest during work, field work), and UI and depression symptoms. However, in contrast to previous studies, none of these variables were associated in our multivariate model [9–11, 19, 39, 51]. Compared to most studies performed in developed countries, our study might be influenced

by other social and ethnic factors [20, 21]. More studies in developing countries are needed to increase the knowledge related to these factors.

A strength of our study is the large sample size of 1284 pregnant women. Further, to gain a broader representation of Nepal's population, data was collected from two hospitals in different districts that care for patients from rural (KUDH hospital) and urban (KIST hospital) areas. Still, the results from our study population might not be generalized to women living in remote areas. Another strength is that we used reliable and valid outcome measures for assessing LBP and PGP, allowing us to compare our results with those from other studies. To our knowledge, the prevalence, severity, and associations of pregnancy-related LBP and/or PGP have not previously been assessed in Nepal using standardized questionnaires. The use of open data kit software for data collection led to very little missing data, further strengthening our study. One possible limitation is that the questionnaires were administered by a research assistant, however, since most of the participants had low levels of education, oral administration was needed to obtain data.

The present study shows that LBP and PGP are prevalent in pregnant Nepalese women and that women experience severe pain intensity alongside a belief in persistent pain post-partum. In developing countries like Nepal, LBP and PGP might be overlooked or considered to be normal complaints during pregnancy [22]. Nepalese women contribute significantly to agricultural and household work, even during pregnancy, and good physical health is needed [15, 16, 44]. Hence, our study highlights the need to address the complaints of LBP and PGP during pregnancy, and for health care providers to deliver timely information and treatment to prevent long-lasting pain.

Conclusions

LBP and PGP are prevalent in pregnant Nepalese women. Despite severe pain intensity, the women experienced low disability. Women with increased BMI, POP symptoms, and husbands with higher education were significantly associated with LBP and/or PGP. Women's belief in poor recovery of LBP and PGP after delivery indicates a need for assessment and information about musculoskeletal complaints in pregnant women in Nepal.

Abbreviations

BMI: Body mass index; CI: Confidence interval; EDS-5: Edinburgh Depression Scale-5; ICIQ-UI SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; KUDH: Kathmandu University Dhulikhel Hospital; LBP: Low back pain; NRS: Numeric Rating Scale; ODI: Oswestry Disability Index; PGP: Pelvic girdle pain; PGQ: Pelvic Girdle Questionnaire; POP: Pelvic organ prolapse; POP-SS: Pelvic Organ Prolapse Symptom Score; SD: Standard deviation; UI: Urinary incontinence; USD: United States dollar

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Authors' contributions

RSA, ATT, MG, MEG, and BS contributed to conception and design, analysis, interpretation of data, manuscript drafting, and critical revision of the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on request.

Ethics approval and consent to participate

Ethical approval was obtained from the Norwegian Regional Ethics Committee, Norway (REK Nord, 2015/2209); The Nepal Health Research Council Ethical Review Board (112/2016), Nepal; The Institutional Review Committee of Kathmandu University School of Medical Sciences/Dhulikhel Hospital (25/16), Nepal. Oral and written consent was obtained from the participants who agreed to participate in this study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

¹Department of Physiotherapy, Kathmandu University School of Medical Sciences, Kathmandu University Dhulikhel Hospital, Kavre, Nepal. ²Institute of Clinical Medicine, University of Oslo, Oslo, Norway. ³Division of Orthopaedic Surgery, Oslo University Hospital, Oslo, Norway. ⁴Department of Physiotherapy, Faculty of Health Sciences, Oslo Metropolitan University, Oslo, Norway. ⁵National Advisory Unit on Rehabilitation in Rheumatology, Department of Rheumatology, Diakonhjemmet Hospital, Oslo, Norway. ⁶FORMI, Oslo University Hospital, Oslo, Norway. ⁷Health Services Research Unit, Akershus University Hospital, Lørenskog, Norway. ⁸Department for Infant Mental Health, Regional Center for Child and Adolescent Mental Health, Oslo, Eastern and Southern Norway, Norway.

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Erratum

Name of candidate: Ranjeeta Shijagurumayum Acharya

Title of thesis: Pelvic girdle pain and pelvic floor disorders in pregnant Nepalese women

Page Number	Original text	Type of correction	Corrected text
5	<p>Reference number 45 to be omitted in the sentence:</p> <p>This strategy has been criticized because of the absence of adequate follow-up consultations and the risk of postoperative complications in rural settings (44-47).</p>	Reference	-
5	<p>To delete one pregnancy as it is repeated twice in the sentence</p> <p>Both PGP and pelvic floor disorders commonly commence during pregnancy pregnancy (48, 49).</p>	Language	Both PGP and pelvic floor disorders commonly commence during pregnancy (48,49).
5	<p>To add reference number 141, 144, 150, 152 in the sentence:</p> <p>“Pelvic floor muscle training (PFMT) is an evidence- based treatment for pelvic floor disorders but there is a lack of studies on PFMT for POP and UI in Nepal (6)”.</p>	Reference	Pelvic floor muscle training (PFMT) is an evidence- based treatment for pelvic floor disorders (141, 144, 150, 152), but there is a lack of studies on PFMT for POP and UI in Nepal (6)”.
16	<p>It should be 50% (not 51%) in the sentence:</p> <p>Based on POP-Quantification, the prevalence is reported to be between 41% and 51% and symptomatic POP ranges from 3% to 10% in high-income countries (26, 119, 121, 122).</p>	Number error	Based on POP-Quantification, the prevalence is reported to be between 41% and 50% and symptomatic POP ranges from 3% to 10% in high-income countries (26, 119, 121, 122).
19	<p>To delete reference number 45 from the first paragraph second last sentence:</p> <p>Moreover, it has been reported that women may require further revision surgeries later, which might be difficult to provide due to a lack of follow-up by the women (43, 45, 46).</p>	Reference	-

20	<p>It should be 45% (not 40%) in the sentence</p> <p>However, studies have reported that 30% to 40% of women was not able to perform PFM contractions correctly (163, 164).</p>	Number error	However, studies have reported that 30% to 45% of women was not able to perform PFM contractions correctly (163, 164).
31	<p>It should be sporting activity instead of physical activity in the sentence:</p> <p>The two items for sex and physical activity have an option of not applicable.</p>	Text	The two items for sex and sporting activity have an option of not applicable.
39	<p>Table 4. Sociodemographic and clinical variables of the pregnant women included in papers I, II and III (n = 1,537)</p> <p>- PGP and/or LBP, n (%): 77 (54)</p> <p>- ICIQ-UI-SF, median (IQR): 0 (0-0)</p>	Number error	PGP and/or LBP, n (%): 137 (54) ICIQ-UI-SF, median (IQR): 0 (0-0)
40	<p>To add IQR (21-38) in the sentence:</p> <p>The median disability total score was 20 (IQR 10–32) for the Nepali PGQ and 30 (21–38) for the Nepali ODI</p>	Text	The median disability total score was 20 (IQR 10–32) for the Nepali PGQ and 30 (IQR 21–38) for the Nepali ODI
50	<p>To delete reference number 220, 221, 222 in the sentence below:</p> <p>Previous studies using EMG biofeedback for PFMT in pregnant women have only included healthy pregnant women (219-222).</p>	Reference	Previous study using EMG biofeedback for PFMT in pregnant women have only included healthy pregnant women (219).
57	<p>It should be able instead of unable</p> <p>Studies have demonstrated that 33% of women were unable to contract the PFMs properly, even after thorough one-to-one instruction (257).</p>	Text	Studies have demonstrated that 33% of women were able to contract the PFMs properly, after thorough one-to-one instruction (257).