

BMJ Open Prevalence of pregnancy-related pelvic girdle pain and associated factors in Australia: a cross-sectional study protocol

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To cite: Cernja D, Chipchase L, Gupta A. Prevalence of pregnancy-related pelvic girdle pain and associated factors in Australia: a cross-sectional study protocol. *BMJ Open* 2017;7:e018334. doi:10.1136/bmjopen-2017-018334

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-018334>).

Received 22 June 2017
Revised 3 October 2017
Accepted 4 October 2017



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ABSTRACT

Introduction Pregnancy-related pelvic girdle pain (PPGP) is a common musculoskeletal disorder. Women with PPGP report difficulty performing everyday functional activities, such as standing and walking. However, the magnitude of the problem remains unknown in Australia. It is important to determine how many women are affected by this condition and the factors associated with PPGP as this will direct healthcare services to being able to better manage women during pregnancy. Thus, this study aims to determine the prevalence of PPGP and associated factors in a Western Sydney population.

Methods and analysis This study is a cross-sectional study to be conducted at a single hospital in Australia. Participants will be over 18 years of age, between 14 and 38 weeks gestation and recruited randomly from all pregnant women attending antenatal care. Participants will have anthropomorphic measures recorded, such as height and body weight, and be asked to complete questionnaires about their current pregnancy, sociodemographic information, ethnoculture, occupational factors and participation in functional activities. The classification of PPGP will be made as per the published guidelines and will include a physical examination.

Ethics and dissemination Ethical approval has been granted by the Human Research Ethics Committees of Westmead Hospital, Sydney, and Western Sydney University, Sydney. Dissemination of results will be via journal articles and conference presentations.

Trial registration number ACTRN12617000904370.

INTRODUCTION

Pregnancy-related pelvic girdle pain (PPGP) describes pain of musculoskeletal origin over the anterior and posterior elements of the pelvic region, between the levels of the posterior iliac crest and the gluteal fold.¹ Women with PPGP report moderate to severe pain which affects everyday activities such as getting up from a chair, bending and walking.² The ability to perform housework, care for children and undertake duties of employment are all diminished, with the major cause of sick leave during pregnancy attributed to PPGP.^{1 3} Women with PPGP report a greater

Strengths and limitations of this study

- The research study will provide information about pregnancy-related pelvic girdle pain (PPGP) that will be useful to healthcare providers, health policy-makers and the patient community in Australia.
- The study will use the recommended guidelines for classification of PPGP, including a physical examination.
- The large sample size allows for investigation of many possible associated factors.
- Given the participants are from one geographical region of Australia with high cultural diversity, the sample may not be considered entirely representative of all Australian women with PPGP.

number of comorbidities, experience negative changes in relationships with family and have more depressive symptoms than pregnant women without pain.^{4 5} In addition, there is decreased health-related quality of life compared with pregnant women without pain.⁶ With such a large impact on function and quality of life, the study and analysis of PPGP is an important epidemiological research priority with the potential to identify healthcare needs.

Prevalence of PPGP

Despite growing clinical interest and an increasing number of publications on this topic in the last two decades, there is a lack of consensus on the incidence and pathogenesis of PPGP.¹ Most of the literature reporting prevalence and describing the epidemiological characteristics of PPGP has been conducted in Europe. These studies have reported prevalence rates ranging from as low as 7% to as high as 84%.^{5 7–19} A major methodological limitation with these studies is that they have not used the same guidelines to classify women with PPGP. Some studies used self-report measures alone, such as pain location drawings and questionnaires,^{5 9 11 16–18}

while others added physical examination to the self-reported measures to confirm a classification of PPGP.^{7 10 12 13 15 19}

In addition to differences in classification methods, not all studies have used the same definition of PPGP.^{5 7–19} Definitions have varied with some studies including participants with pain reported in the lumbopelvic region, without distinguishing pelvic girdle pain from low back pain.²⁰ Some studies have been prospective, while others were retrospective which introduce the possibility of recall bias. Hence, comparison between studies is problematic and may explain the large range in the published data on prevalence rates.

Only one study investigating prevalence of PPGP has been conducted in Australia.¹⁷ Here, the prevalence of PPGP was reported to be 23% in a snapshot of pregnant women attending antenatal care at a single hospital over the period of 1 week. However, the sample size was small (n=95) and one of convenience, which impacts on the ability to determine whether this rate is representative of the prevalence at the institution and in the wider Australian community. Further, the study did not classify women as having PPGP according to recommended guidelines. Therefore, information about prevalence rates using the recommended guidelines for classification of PPGP is needed to accurately quantify the size of the problem in Australia. This information is important to determine appropriate healthcare services and funding, including timely assessment and effective management of women with PPGP. Currently, many women do not receive adequate information about PPGP and may not be aware that there are appropriate management strategies which may benefit them.²¹ In turn, effective management may reduce the socioeconomic burden associated with PPGP.

Factors associated with PPGP

There has been limited investigation into factors associated with PPGP in Australia. Previous studies in other regions of the world have not revealed one single causative factor. However, a history of low back pain, previous PPGP and psychological distress have been reported to be strongly associated with PPGP.^{5 7 11 12 15–17 19 20 22 23} In contrast, associations for age, parity, exercise levels, work history, job satisfaction and education levels with PPGP have demonstrated conflicting findings.^{11–15 17 19 22 23} For example, some studies report an association between parity and PPGP, whereas others have not.^{9 11–15 17 19 22}

Another issue determining factors associated with PPGP is that not all possible factors have been investigated. Clinical, anecdotal evidence suggests that time spent in everyday activities, such as standing and walking, may be associated with PPGP. Only one published study has examined the association between functional activity and PPGP, with women who used stairs regularly more likely to report PPGP.¹⁷ Familial or hereditary links have also been suggested to be a factor.^{13 24} Two previous studies have reported that women who have a mother or sister with a history of lumbopelvic pain during pregnancy

have an increased risk of pain.^{13 24} However, neither study distinguished between PPGP and low back pain. Therefore, further investigation is warranted into family history in women with PPGP. Finally, factors such as ethnicity, have not been investigated extensively either with only one study reporting prevalence rates and factors associated with PPGP between ethnic groups in one European country.²⁵ As there is considerable evidence demonstrating that ethnicity is associated with other musculoskeletal pain disorders, such as low back pain,²⁶ investigation of the association between ethnicity and PPGP is needed. This is particularly the case in an Australian population in which one-third of the population was born overseas.²⁷

Aims of current research

This study aims to:

1. Determine the prevalence of PPGP in a Western Sydney population.
2. Investigate factors associated with PPGP in a Western Sydney population.

METHODS AND ANALYSIS

Design

This is a cross-sectional study to be conducted at Westmead Hospital in Sydney, Australia. Westmead Hospital is a large teaching and tertiary referral government-funded hospital in an urban centre, with over 5500 live births recorded annually.²⁷ This study will be conducted over a period of 18 months, from October 2017 to April 2019.

Data collection and sample size

Inclusion criteria

All participants of this study must be over 18 years of age, between 14 and 38 weeks gestation and have sufficient command of written and spoken English language or have a healthcare interpreter present to be able to complete survey questionnaires. Exclusion criteria will include any medical or obstetric complication(s) which affects their pregnancy, such as serious pathology of non-musculoskeletal origin including pre-eclampsia, eclampsia, serious intellectual or psychiatric impairment, systemic disease(s) or recent spinal fracture, trauma or surgery.

Recruitment

A simple random sampling method will be used for recruitment, which will be conducted through the antenatal clinic at Westmead Hospital. Pregnant women attend the antenatal clinic on scheduled appointments during their second and third trimesters. A sample of all pregnant women booked to attend antenatal care at the hospital will be randomly generated from the daily clinic attendance list prior to the researcher attending the antenatal clinic on a given day. The random sample will allocate a number to each woman booked into the clinic in the order in which they may be approached and invited to participate. Therefore, if one woman

declines to participate, then the next woman on the list may be approached, as an iterative process for all women presenting to the antenatal clinic on a given day. The researcher will inform potential recruits of the study both verbally and with written information. Those agreeable to participate will be required to provide written and informed consent to be included in the study. Those who decline to participate in the study will continue to receive their hospital antenatal care as usual. The antenatal care provided to each pregnant woman will not be affected nor influenced by the woman's decision to either participate or not participate in the study. Each participant will be assessed by a physiotherapist during a single session in the antenatal clinic at Westmead Hospital. Participants will not be assessed on more than one occasion.

Sample size

The sample size required is 770 and is based on calculations from a previous study investigating prevalence of PPGP at Westmead Hospital.¹⁷ The 95% CI for estimated prevalence will be no less than or greater than 3% with 770 participants. Assuming independent samples t-test (two tailed) with 90% power and alpha=0.05 significance level, this study is powered to detect a 0.28 SD difference in means between the two groups (those with PPGP and those without PPGP) ($G \times \text{power}$).²⁸

MEASURES

Primary measure

The main focus of this study is to determine the point prevalence of PPGP in Australian pregnant women. To determine whether the participant has or does not have PPGP, each participant will be asked to complete a body chart, indicating the area in which they have pain or have experienced pain within the previous 24 hours. Participants who do not report any pain in the lumbopelvic region will be classified as not having PPGP. Participants who indicate that they are experiencing pain in the lumbopelvic region will undergo a clinical examination according to recommended guidelines to classify whether they have PPGP and include a combination of self-report on symptomology, impact on activities of daily living and a physical examination.²⁹ These guidelines distinguish between pregnancy-related low back pain and PPGP. To be classified as having PPGP, participants will report the specific pain location to be in the region distal to fifth lumbar vertebrae and between the posterior iliac crest and the gluteal fold with or without pubic symphysis pain. The pain drawings on body chart figures completed by the participant allow for differentiation of pain between low back pain and PPGP.¹⁹ Women classified as having PPGP will confirm during an interview that the pain commenced during pregnancy and will report pain during two or more of the following activities: walking, standing, climbing a flight of stairs, turning over in bed or getting out of a chair. At least two of the following physical examination tests will be positive on the side of the reported symptoms:

posterior pelvic pain provocation (P4) test,³⁰ palpation of long dorsal sacroiliac ligament,⁷ active straight leg raise (ASLR) test³¹ and modified Trendelenberg test.⁷ Previous studies have recommended the use of several tests to accurately diagnose and classify PPGP.^{10 29 32–35} All tests have excellent reliability and validity, with very high specificity.²⁹ The ASLR test has been chosen as it has been used extensively to inform classification of PPGP.^{19 29 31 36} The modified Trendelenberg test has been used as a provocation test for symphysis pubis pain in the classification of PPGP.^{7 29 34 35 37 38}

Secondary measures

A number of secondary measures will be included to investigate factors associated with PPGP. Secondary measures will include anthropomorphic measures, such as height and weight. Participants will be asked to provide information by completing questionnaires about their current pregnancy, including age, gestation of pregnancy, parity (defined as previous deliveries greater than 24 weeks gestation) and pregnancy type (singleton or multiples, such as twins, triplets, etc). Sociodemographic information will also be recorded by determining the participant's marital status (married, not married or de facto) and education level (primary school completion or less, attended high school but did not finish, finished high school, university degree completion).¹¹ Participants will be asked about ethnocultural factors, including the country of birth of the participant, their mother and their father (according to the Australian Bureau of Statistics list of country of birth)³⁹ and self-identified ethnicity (according to the Australian Bureau of Statistics list of standard classifications of culture and ethnic group).⁴⁰ Participants will be asked whether they have a history of previous low back pain (LBP) and/or PPGP which is not pregnancy related. Participants with a parity of one or more will also be asked if they have a history of previous LBP and/or PPGP which was experienced in an earlier pregnancy. Participants will be asked if there is family history with their mother and/or a sister having PPGP. Participants will be asked to complete a questionnaire about occupational factors, including work status (hours of work defined as none, 0–20 hours, 20–40 hours and more than 40 hours per week), work type (a five-level scale running from very heavy to very light) and work satisfaction (a five-level scale running from very bad to very good).¹¹ Current activity levels will be determined by the physical activity and pregnancy questionnaire⁴¹ and the Pregnancy Mobility Index⁴² which have been shown to be reliable and valid measures in pregnancy. Participants will be asked about time spent in daily positions, such as hours spent lying down, sitting, standing and walking in a typical day.⁴¹ The Pelvic Girdle Questionnaire, a reliable and valid measure for evaluating symptoms and disability in PPGP, will be administered.^{38 43} Finally, participants will be asked to rate their current pain level and the pain level over the past 24 hours using a visual analogue scale (VAS).⁴⁴ For the VAS, participants will be instructed to score their pain

intensity on a 0 (no pain) to 100 (worst possible pain) point scale, anchored by word descriptors.

Risk of bias

To reduce the risk of recruitment bias, all women attending antenatal care on a given day at the hospital will be randomly allocated a number starting at 1 to create a list of the order in which women will be approached and invited to participate in the study. It is expected some of these women will be excluded from the study based on exclusion criteria, and some women will not volunteer to participate. Therefore, to ensure the study sample is representative of all women attending this hospital for antenatal care, demographic data obtained from participants will be compared with data available about the general population of pregnant women attending antenatal care at Westmead Hospital. The data collection will be performed by one physiotherapist. However, the included physical examination tests have been shown to have excellent reliability.^{7 29} To reduce assessor bias, prior to the study commencement, the assessing physiotherapist and one other physiotherapist (not part of this study research team) will determine the interexaminer reliability of the four physical examination tests, in which 20 pregnant women with self-reported PPGP will be tested to investigate the agreement between two independent physiotherapists. Further, it is of note that the physical examination is only one component out of a total of four in the classification of PPGP process.

Statistical analyses

Data will be analysed in SPSS V.23 and presented in tables, charts and/or graphs. The prevalence of PPGP will be calculated by dividing the number of women classified with PPGP by the total number of women participating in the study. Logistical regression will model prevalence rates according to gestational age and allows for an estimation of the effect of gestational age on PPGP.

Factors associated with PPGP will be identified with appropriate parametric comparisons between the two groups (women with PPGP and women without PPGP). Non-parametric tests will be used where data are not normally distributed. Categorical variables, such as marital status and education level, will be compared across the two groups using χ^2 test or Fisher's Exact test, depending on the cell size, to detect if there is a statistically significant difference between groups of women with and without PPGP. For continuous variables, such as pain intensity score, the student t-test or Mann Whitney U test will be used to detect if there is a statistically significant difference between groups.

Multiple logistic regression analyses will be used to identify the associations with PPGP and interactions between these factors on PPGP. Multiple logistic regression analyses will also allow determination of the covariance among these variables. Selection of variables in the model will be informed by previous research findings and observed statistical significance between the two groups

(women with PPGP and women without PPGP) from this study.

Data monitoring and management

Data entry will be performed by the same researcher to reduce risk of data entry which may occur when multiple people are involved in data entry methods. To ensure accuracy of data entry with such a large sample size, a random sample from all participants will be checked by other members of the research team to ratify data entry. Data will be stored securely at the research site. Paper documents will be kept in a locked drawer of a filing cabinet and electronic data will be stored on password-protected desktop computer files which can only be accessed by a member of the research team. Data will be stored in a non-identifiable manner whereby all participants will be anonymous.

Ethics and dissemination

All study participants will provide written informed consent and will receive written information about the study, including the contact details of the Westmead Hospital Human Research Ethics Committee, so that they are able to report any concerns or complaints about the study. The study has been registered in the Australian and New Zealand Clinical Trials Registration database (ACTRN12617000904370). The Universal Trial Number (UTN) is U1111-1197-4846.

Findings of the study will be disseminated in peer-reviewed publications in journals and will be presented at international and national conferences. Media releases will be considered to increase the opportunities to disseminate findings to the general public.

DISCUSSION

This protocol outlines the rationale and design for a cross-sectional study that aims to determine prevalence of PPGP and associated factors in an Australian population. The prevalence of PPGP in the Australian community has received little attention. Improving knowledge about PPGP may influence the amount and type of healthcare women receive and hence reduce the widespread burden associated with PPGP.

The strengths of the study include use of recommended guidelines for PPGP classification to ensure accurate prevalence rates. The large sample size also allows for a comprehensive investigation of factors associated with PPGP, including ethnoculture and functional activity which have not been previously investigated.

This study may be limited by its external validity as it will only include participants from one hospital in one geographical region of Australia. Westmead Hospital is a specialist tertiary referral and major teaching hospital in Western Sydney, in the state of New South Wales. The hospital has a catchment which includes women from a diverse range of socioeconomic situations, ethnocultural backgrounds, educational levels and working status. Therefore, the population may be different to other

parts of Sydney and Australia and not representative of the prevalence of PPGP in those geographic regions. However, collecting data on a large sample (n=770) will ensure that the sample represents the wide diversity of women residing in Western Sydney and is similar to the diversity of the population in parts of other urban centres in Australia, such as Melbourne and Brisbane. Thus, it provides a valuable opportunity to determine whether PPGP is a condition which is as prevalent in this Australian population as has been reported in other countries. Further, the use of well-validated measures, including the Pregnancy Mobility Index and Pelvic Girdle Questionnaire, in this study may allow a comparison of the sample population of women with PPGP to those described in previously published studies.

In summary, the exact size of the problem of PPGP in the Australian community is unknown. More information about the prevalence of PPGP and associated factors has the potential to influence health resource use, thus improving the pregnancy experience and health outcomes for many women.

Contributors DC, AG and LC were involved in the design of the trial. DC drafted the manuscript. AG and LC edited the manuscript. All authors have approved the final version.

Competing interests None declared.

Ethics approval Ethical approval has been granted by the Human Research Ethics Committees of Westmead Hospital, Sydney (HREC/17/WMEAD/64), and Western Sydney University, Sydney (RH12294).

Provenance and peer review Not commissioned; externally peer reviewed.

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