The Predictive Value of the Active Straight Leg Raise on the Efficacy of a Sacroiliac Joint Belt in Posterior Pelvic Girdle Pain during Pregnancy

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Background and Significance

During pregnancy, women often experience musculoskeletal pain, specifically in their low back and/or pelvic girdle. Pelvic girdle pain (PGP) is defined as pain between the posterior iliac crest and gluteal fold, particularly in the region of the sacroiliac joint (SIJ)[1]. Although it is often referred to as “sciatica”. PGP in pregnancy is common with prevalence estimates of 45%[2]. Previous studies have found that one third of patients will rate their PGP intensity as severe, leading to functional impairments. Functional disabilities include sitting, walking, and standing; thus, significantly impacting the ability of patients to perform routine daily activities. This pain has been reported to develop as early as 17-19 weeks’ gestation, lasting up to 3 months postpartum; with a peak incidence of 24-36 weeks.

The etiology of PGP in pregnant women is still not fully understood, largely due to the complex interactions between bone, ligaments, fascia, and muscles in the pelvic joints[3]. Some studies suggest the increased mobility of the joints in the pelvic girdle during pregnancy due to relaxin cause a lack of stabilization in the sacroiliac region, which results in pain[4]. Thus, it is hypothesized that providing stabilization of the joints with an external force, such as a maternity or SIJ belt, will improve pain.

Clinically, pelvic belts are often used as a part of a multimodal approach to reduce PGP alongside other conservative treatments such as analgesics and physical therapy, or more alternative treatments such as acupuncture[5]. This makes it difficult to determine their individual effect on pain reduction. Further confounding this issue are variations in physician counseling, physical therapy regimens, and analgesic usage. Moreover, several support belts have been designed that vary in padding size, flexibility, and site of application[5-7]. Among these belts, it has

not yet been identified which belt is most beneficial regarding pain reduction and patient tolerance[5]. Previous studies have found benefit in short term use (3-6 weeks) of maternity belts, providing women with improved pain and function compared to exercise or no intervention[7]. Pelvic belts are a cost-effective option to treating PGP, and more specifically SIJ pain, yet studies are limited regarding the effect they have on SIJ mobility and pain reduction[8] and more specifically determining what clinically predicts those who will benefit most from an SIJ belt.

The active straight leg raise test originally described by Mens is an examination maneuver that measures functional mobility and has been correlated with pregnancy related PGP (cite). Anecdotally, our clinical team has observed that women who benefit from compression during the second part of the test, seem to benefit most from the use of an SIJ belt. Having a simple test for obstetric providers to perform in pregnant women with pain would be informative in determining who might benefit most from an SIJ belt. Hence our study seeks to investigate the following aims:

Study Aims:

Aim 1. To determine if the Active Straight Leg Raise (ASLR) severity score is immediately reduced by application of a sacroiliac (SIJ) belt in women with PGP during pregnancy

Hypothesis: The application of an SIJ belt will reduce the score of the ASLR by 2 points.

Aim 2. To determine if the initial ASLR score change predicts pain reduction with use of an SIJ belt in women with PGP during pregnancy

Hypothesis: PGP NRS score will be reduced by 2 points.

Study Design: a prospective observational cohort study.

Study Procedures:

Patients will be approached in their second or third trimester regarding the study in the Obstetrics or Rehabilitation clinics if they have PGP. If interested in participating, they will either proceed to study visit 1 (baseline), if time permits, or set up a separate time for study visit 1 to take place. Patients will be consented and evaluated for eligibility at this baseline visit. Eligible patients will be complete questionnaires, undergo a standardized musculoskeletal exam and SIJ belt fitting at Study Visit 1. After SIJ belt fitting the ASLR test will be repeated with the belt in place. This study will require 2 study visits total, study visit 1 will be at the time of consent, study visit 2 will be 4 weeks after baseline. Study duration is 4 weeks per patient. At study visit 1, patients will undergo a physical examination of the external musculoskeletal pelvis and will complete the NRS for 'worst pain' and 'mean pain' during the latest 48 hours, a pain diagram, a personal health information questionnaire regarding their pregnancy, past medical history, activity level and restrictions and disability as measured by the Pelvic Girdle Questionnaire (PGQ).

Standard physical examination maneuvers validated for the assessment of pregnancy related PGP will be performed by the PI Dr. Fitzgerald and include pelvic pain provocation tests and functional stability testing. It will be noted with each maneuver whether the test was positive or negative. They will include:

a. *Patrick's Faber test*: With the patient in supine, the patient's leg is flexed, abducted and externally rotated so that the heel rests on the opposite kneecap. This test is positive with production of pain in the sacroiliac joint.

b. *Posterior Pelvic Pain Provocation (P4) test:* with the patient supine, the femur is flexed to be perpendicular with the table at 90 degrees and the knee is flexed at 90 degrees. A gentle force is applied to the femur in the direction of the examination table. The test is positive when the

patient experiences pain in the gluteal region of that leg.

c. *Long Dorsal Sacroiliac Ligament (LDL) palpation test*: The subject lies on her side with slight flexion in both hip and knee joints. Specifically, the LDL is palpated directly caudomedially from the posterior iliac spine to the lateral dorsal border of the sacrum if palpation causes pain that persists five seconds after removal of the examiner's hand, it is recorded as pain. If the pain disappears within five seconds, it is recorded as tenderness. When the identical pain is felt directly in the vicinity, but outside the borders of the ligament, the test is not deemed as positive.

d. *Pubic Symphysis palpation test*: Examiners will palpate the subject's pubic symphysis joint while the patient is lying supine for tenderness. If palpation causes pain that persists five seconds after removal of the examiner's hand, it is recorded as pain. If the pain disappears within five seconds, it is recorded as tenderness.

e. *Modified Trendelenburg's test*: The standing woman stands on one leg and flexes the other at 90° (hip and knee). The test is considered positive if pain is experienced in the symphysis.

f. *Active Straight Leg Raise (ASLR) test*: performed with the patient supine with straight legs extended on the table 20 cm apart. The patient raises each leg one at a time 20 cm above the table without bending the knee. A) The test is positive when the patient describes a heaviness or difficulty in performing the task. B) In the second part of the maneuver, posterior compression is applied and the patient is then asked to actively perform a straight leg raise. If there is greater ease in lifting the leg this is considered a positive test. The patient will be asked to score impairment (scoring inadequacy to raise the legs but not pain) on a 6-point scale: not difficult at all = 0, minimally difficult = 1, somewhat difficult = 2, fairly difficult = 3, very difficult = 4, unable to do = 5, the scores of both sides will be added so that the summed score can range from 0-10. Impairment is considered severe if the summed bilateral score is at least 4.

Personal Health Information to be collected: The personal health information (PHI) items that will be collected during pregnancy will include: name, phone number; date of birth; BMI;

height; age; race; education level; income level; number of previous pregnancies; number of previous deliveries; types of previous deliveries, past abdominal surgeries if any, current medications; history of other pain diagnoses, history of depression; history of neurological disease; history of anxiety; history of sexual abuse; previous low back injury; previous low back or pelvic pain; history of smoking; history of infertility; history of urinary or fecal incontinence; history of interstitial cystitis; history of arthritic conditions (osteoarthritis, rheumatoid arthritis, lupus); body parts affected by arthritic conditions; diabetes (Type I, Type II, gestational); gestational week of current pregnancy; due date of current pregnancy; number of babies expected; trimester/gestational week of onset of pelvic girdle pain, current pregnancy complications; activity and exercise types and levels during pregnancy; activity level restrictions; and if participated in physical therapy, the number of visits completed. Social history including marital status, support at home, and type of occupation will be documented.

All patients will receive and be fitted by the PI Dr. Fitzgerald with an SIJ belt. Study visit 2 will follow-up PHI, the pain NRS and PGQ questionnaires, the Patient Global Impression of Improvement (PGII) scale and physical examination limited to the ASLR.

Inclusion criteria:

- English speaking pregnant women presenting in their second or third trimester with posterior PGP. Trimester will be determined from date of last menses or ultrasound date.
- Pain must be between the upper level of the iliac crests and the gluteal folds in conjunction with or separately from pain in the pubic symphysis and influenced by position and locomotion
- ASLR score between 2-10

Exclusion criteria:

- Non-English speaking pregnant women <18 or >50 years old
- Women presenting with PGP in the first trimester (<13 weeks gestation)
- Women with pubic symphysis (anterior) pain alone
- Pain above the upper level of the iliac crest
- ASLR total score of <2
- History of lumbar or pelvic fracture, neoplasm, inflammatory disease, active urogenital infection or active gastrointestinal illness, previous surgery of the lumbar spine, pelvic girdle, hip joint or femur
- History or signs of radiculopathy or other systemic neurologic disease

Consent process

Patients will be identified when they arrive for a scheduled MD appointment at any point during their second or third trimester. If the patient meets eligibility criteria, a consent form will be read to them describing the nature of the study and potential associated minimal risks and benefits. They will be informed that neither participation nor refusal will influence the care received at Loyola University Medical Center. They will be asked a few questions afterwards to verify comprehension and then sign the consent form documenting their agreement to participate. A copy of the consent form will be given to them. Participation is completely voluntary and they may discontinue participation in the study at any time. Patients will complete the informed consent process at study visit 1. A study coordinator (Mary Tulke) or the PI (Dr. Fitzgerald) will consent all patients. The patients who consent to participate will be given a set of questionnaires at that time and asked to complete them during study visit 1. Consenting patients will undergo systematic examination procedures. These procedures will be performed by the PI. Patients will receive free SIJ belts.

Follow-up

All patients will be asked to participate in a study visit 2 follow-up in person. Questionnaires (NRS, pain diagram, PGII, PGQ and personal health history information along with estimated belt wear time and other pain interventions (Physical therapy, medications, ice, heat) will be collected. Only one repeat physical examination maneuver the ASLR will be done.

Adverse event reporting:

The PI or the study nurse coordinator can be reached by pager or phone. Dr. Jean Goodman, division chief Loyola Maternal Fetal Medicine will also be available for any patient adverse reactions. If any unanticipated adverse event occurs, this will also be immediately reported to the IRB.

Confidentiality

Following HIPPA guidelines, patient identifiable data will be coded to protect each patient's identity. The data obtained from the patients will be entered onto electronic forms and imported into a REDCap database. We are familiar with using this technology from other studies. It is efficient to complete in a clinical setting and minimizes data entry errors. The data will be presented in peer reviewed manuscripts and other public presentations at the group level only. No individual patients will be identified.

Here is an overview of the security of the infrastructure:
Physical
- Servers kept in locked cage
- Entry requires a passcard and biometric recognition
- Digital surveillance equipment
- Controls for temperature, humidity and smoke/fire detection
- Staffed 24/7 Network
- Multiple independent connections to Tier 1 Internet access providers
- Fully redundant OC-48 SONET Rings
- Uptime monitored every 5 minutes, with escalation to SurveyMonkey staff
- Firewall restricts access to all ports except 80 (http) and 443 (https)
- QualysGuard network security audits performed quarterly

Hardware
- Servers have redundant internal power supplies
- Data is on RAID 10, operating system on RAID 1
- Servers are mirrored and can failover in less than one hour

Software

- Code in ASP, running on SQL Server 2000 and Windows 2000 Server
- Latest patches applied to all operating system and application files
- Data backed up every hour internally
- Data backed up every night to centralized backup system, with offsite backups in event of catastrophe

Sample size;

In this study, patients will complete a baseline active straight leg rise (ASLR) evaluation, which is a functioning assessment performed on each leg using a scale from 0 to 5. For this assessment, the summed score for both legs will be recorded where higher values indicate greater impairment. Patients who receive a summed value of 2 or higher will continue in the study and will receive belt therapy for 4 weeks (described above). At the end of these 4 weeks, patients will complete a final ASLR assessment.

One goal of the proposed study is to test the null hypothesis that the mean difference (or change) in patients' active straight leg rise score from baseline to 4 weeks is 0. Power is computed to reject this null hypothesis and assumes that the population from which the sample will be drawn has a mean decline of 2.0 SLR points (with a standard deviation of 5.0 SLR points). This observed value will be tested against the theoretical value (constant) of 0 SLR points.

To account for patients determined to be ineligible or lost to follow-up, a total of 70 patients may be consented. Recruitment will end when 52 patients have completed the study. With the proposed sample size of 52 pairs (i.e., 52 patients with both a baseline and 4 week SLR measurement), the study will have power of 80.8% to yield a statistically significant result. This computation assumes the criterion for significance (alpha) has been set at 0.05 and that the test will be 2-tailed, which means that an effect in either direction may be interpreted. This computation also assumes that the anticipated mean difference is the smallest effect that would

be important to detect, in the sense that any smaller effect would not be of clinical or substantive significance.

Analysis

In this study, the primary alternative hypothesis is that the mean difference in patients' total straight leg rise (ASLR) score from baseline to 4 weeks is significantly different from zero. A 2-sided paired samples t-test will be used to test this hypothesis. The change in ASLR from baseline to 4 weeks will be evaluated for normality using QQ plots and, if this difference is not normally distributed, a distribution-free non-parametric Wilcoxon signed-rank test will be used to test the hypothesis.

Assuming the parametric assumptions of linearity, normality, and homogeneity are satisfied, this study will also use a linear mixed effects model to estimate the adjusted mean difference in ASLR after controlling for other important covariates collected during this study. For example, one goal will be to estimate the mean difference in ASLR score after controlling for patients' age, BMI, past abdominal surgeries, and number of prior deliveries, all of which are known to affect active straight leg rise scores. In this model, random intercepts will be allowed for each patient to account for their repeated ASLR scores (i.e., within subject correlation).

Regarding the secondary aim, the alternative hypothesis is that any change in patients' pain from baseline to 4 weeks is a function of their mean ASLR difference score. For this aim, a linear mixed effects model will be used to estimate the mean change in pain for each one unit decrease in the ASLR change score. As before, this model may control for other important covariates collected during the study, including patients' age, BMI, past abdominal surgeries, and number of prior deliveries. Due to the use of repeated pain assessments as well as

repeated ASLR assessments, random intercepts will be allowed for each patient in order to account for their within subject correlation.

All analyses will be completed by the Biostatistics Core in the Clinical Research Office at Loyola University Chicago Health Sciences Division using SAS version 9.4 (Cary, NC).

Risks and Benefits:

Fetal Risk and Benefit

There is no benefit or risk in this study to the fetus aside from the potential long term benefit of better maternal pain control in the postpartum period that would influence maternal-child bonding and childcare.

Maternal Risk and Benefit:

The risk to the mother is also minimal. Mothers with moderate to severe pain have significant disability that affects current and future quality of life. The potential benefit of the pain treatment outweighs the minimal risk. All patients will be offered standard of care physical therapy (cost covered by their insurance), a proven treatment for pregnancy related pelvic girdle pain.

The benefits of the intervention include the possibility of superior pain relief and improved mobility with use of SIJ belt. The principal investigator and/or study physician will evaluate (1) The expected relationship of the event with the study intervention and (2) Whether any action should be taken regarding the study intervention following an adverse event.

Anticipated findings and use of the data:

The findings from this project may result in pain reduction and improved mobility in pregnant women

Subject compensation:
Subjects will receive the SIJ belt free and parking sticker at follow-up visit.

References:

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