

Integrative Chiropractic Care in a Perinatology Clinic: A Pilot Study

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Research Plan

a. Specific Aims

The broad long-term objectives of this project are to improve the maternal and prenatal outcomes in malposition and/ or malpresentation. The specific aims of this project are to:

1. Determine the feasibility of integrating chiropractic care with medical care in patients with malposition and/or malpresentation.
2. Compare the effectiveness of standard medical care alone versus chiropractic care integrated with medical care in decreasing the musculoskeletal symptoms associated with pregnancies.
3. Determine the effectiveness of the Webster Technique in correcting fetal malposition and malpresentation.
4. Determine if rates of caesarean section, external cephalic version or vaginal births are affected by integration of chiropractic care.
5. Determine whether further research is warranted.

b. Background and Significance

According to Hickock et al. (1), approximately 3-4% of pregnancies reach term with breech fetal presentation. The medical management options in such situations were to offer the patient the external cephalic version, to perform planned caesarean section or to aim for vaginal birth. The publication of the Term Breech Trial by Hannah et al. (2), wherein findings of significant reduction in adverse perinatal outcomes without an increased risk of immediate maternal morbidity with planned cesarean delivery compared with planned vaginal birth.

corroborates the increasing reluctance in birth centers to allow for vaginal births. The option now lies between external cephalic version (ECV) and elective caesarean section (CS).

Hofmeyr (3) searched the Cochrane Pregnancy and Childbirth Group trials register and the Cochrane Controlled Trials Register to assess the effects of external cephalic version for breech presentation before term on measures of pregnancy outcome. ECV was found to have no significant effect on non-cephalic presentation, on caesarean section, on low Apgar scores and perinatal. The study concluded that ECV before term does not appear to improve pregnancy outcomes. At term, ECV appeared to reduce the chance of non-cephalic births and caesarean section (4). Hofmeyr and Kulier also found that not enough evidence exists to assess any risks of ECV at term. However, according to others; ECV has been known to carry certain risks including cord prolapse and entanglement, placental abruption, and feto-maternal haemorrhage. Additionally, following a successful ECV, women are at higher risk for caesarean section (5).

With respect to caesarean sections, Hofmeyr and Hannah (6) searched the Cochrane Pregnancy and Childbirth trials register and the Cochrane Controlled Trials register to assess the effects of planned caesarean section for breech presentation on measures of pregnancy outcome. They found that planned caesarean section greatly reduces both perinatal/neonatal mortality and neonatal morbidity, at the expense of somewhat increased maternal morbidity.

Given the above findings, ECV and CS should not be the only obstetric intervention options. Indeed, as adult utilization of so-called complementary and alternative medicine (CAM) continues to increase (7), women with breech pregnancies are turning to CAM as a management option. A Medline search on the use of CAM in breech pregnancies using the subject headings "breech presentation AND alternative medicine" revealed a handful of alternative approaches. One involves the use of auricular plaster therapy (8). A second involves the use of homeopathy (9). A third is the use of hypnosis (10). A fourth group used acupuncture (11). A fifth, the use of a called moxibustion, a traditional Chinese method of treatment, which utilizes the heat generated by burning herbal preparations containing the plant *Artemisia vulgaris* to stimulate the acupuncture points (12). And sixth, a chiropractic procedure called the Webster Technique (13). Except for hypnosis and homeopathy, the above alternative methods report a greater than 80% success rate in correcting the breech presentation.

b. Preliminary Studies/Progress Report

Musculoskeletal disorders are common in normal pregnancy, and high incidences have been described in several studies. Nine-month prevalence rates for low back pain ranging 48-90% have been reported (14-16). Several biomechanical and physiologic changes during pregnancy contribute to the pathophysiology. As the woman's abdominal muscles are stretched and tone is diminished, they lose their ability to contribute to neutral posture. During pregnancy, production of the hormone relaxin increases ten-fold. The hormone creates joint laxity, which not only allows the pelvis to accommodate the enlarging uterus, but also weakens the ability of static supports in the lumbar spine to withstand shearing forces. In the pelvis, joint laxity is most prominent in the symphysis pubis and the sacroiliac joints. (17).

Given the success of chiropractic care in patients with low back pain (18-21), pregnant women are seeking care from chiropractors. Daly et.al. (22) reported that after manipulative therapy to the sacroiliac joint, 10 of the 11 women reported relief of pain and no longer exhibited signs of sacroiliac subluxation. Diakow (23) performed a retrospective study of 400 pregnancies and deliveries undertaken by interview of 170 consecutive female patients presenting to five chiropractic offices. Back pain was reported during 42.5% (n=170) of the pregnancies and 44.7% (n= 179) of the deliveries. There was a statistically significant association between back pain during the two events. Of the 170 pregnancies with reported back pain, 72% (n=122) also reported back labor. A subsample of 170 painful pregnancies was divided into those that had received manual manipulation and those that had not. The treated group experienced less pain during labor. Additionally, chiropractic care using the Webster Technique may provide a non-invasive method of addressing fetal malposition and malpresentation. Recently, Pistolesse (13) surveyed members of the International Chiropractic Pediatric Association (ICPA); regarding the use of the Webster Technique for managing the musculoskeletal causes of intrauterine constraint. The surveyed doctors reported a high rate of success (82%) in relieving the musculoskeletal causes of intrauterine constraint using the Webster Technique. The Webster Technique is a specific chiropractic adjustment which removes interference to the nervous system, balances out pelvic muscles and ligaments which in turn removes constraint to the woman's uterus, thus allowing the baby to get into the best possible position for birth. The technique on pregnant women does not convey any risk to the mother or fetus because it reinstates proper pelvic

biomechanical movement, facilitates the fetus to reposition itself, and does not use forceful manipulation. The International Chiropractic Pediatric Association provides a post-graduate Certification Program in the technique. At present, over 1200 practitioners have been certified and currently utilize the procedure in their private practices on pregnant women. No reported adverse reactions have ever been reported. This is corroborated by the findings of Phillips et.al. (24). Phillips et.al. performed a retrospective, case-matched, static-group comparison study to determine whether the addition of chiropractic care including a regimen of standard obstetric pregnancy results in fewer obstetric interventions during labor and delivery. Following selection and matching criteria, 35 patients were selected for the study. Conclusively, the study provided evidence that the addition of chiropractic care during pregnancy results in any observable benefit to the patient, no detriment with regard to obstetric interventions used during labor and delivery and that chiropractic care for pregnancy-related neuromusculoskeletal disorders do not complicate labor or delivery.

Anrig and Plaughter (25) put forth that the Webster Technique is safe, effective and with less risk than the ECV procedure for breech presentation. The ECV has been known to result in uterine rupture, premature placental separation, fetal-maternal hemorrhage and failure. Concomitantly, the Webster Technique may also provide a non-invasive prophylactic to cesarean section delivery. To the best of our knowledge, this is the first study to investigate the effects of chiropractic care via the Webster Technique in patients with fetal malposition/malpresentation integrated with a traditional medical facility as outlined below.

c. Research Design and Methods

The study design is pre-experimental utilizing a pre-test/post-test and static group comparison design.

Study sites

The study will be conducted at [chiropractic clinic] and [medical clinic]. Informed consent will be sought from all study participants.

Recruitment of Subjects

Patients will be recruited from patients referred from the medical clinic. Participation in the study is strictly voluntary and the patient may withdraw from the study at any time. The

recruitment time may take from 3-6 months dependent on the number of subjects obtained within this timeframe.

Subjects:

A minimum of 50 subjects will be recruited for the study to receive chiropractic care in addition to their medical care. The comparison group will also have an equal number of patients.

For all subjects:

Inclusion Criteria

1. Willingness to give informed consent
2. Agree to follow study protocol (i.e., undergo ultrasound imaging, attend visits to the chiropractor, fill out questionnaires, etc.)
3. Malposition and malpresentation as identified by ultrasound imaging at 20-40 weeks of gestation.

Exclusion criteria

1. Pre-existing co-morbidity that presents a contraindication to spinal manipulative therapy.

Interventions

Medical Care:

All patients will be medically managed by a perinatologist throughout the study. The medical treatment will follow standardized guidelines for the management of pregnancies with malposition and/or malpresentation.

Chiropractic Care:

A licensed, experienced chiropractor with certification in the Webster Technique will deliver the care throughout the study. Chiropractic care will consist of up to 3 visits per week (as indicated). With each visit to the chiropractor, the following management outline will be followed:

1. Maternal Postural Exam
2. Motion examination and assessment of PSIS joint
3. Palpation of sacrum for posteriority
4. Prone examination of sacral posteriority based on Webster leg resistance check.

5. Supine exam and assessment of lower right quadrant of female abdominal region for location of origin and insertion of round ligament and location of tension in the round ligament.
6. Webster Technique

Outcome measures

In addition to patient demographics such as age, birth histories, etc., the following outcome measures are scored.

Questionnaires

The following questionnaires will be administered at baseline and at last visit:

- 1 SF 36
- 2 Oswestry Disability Questionnaire

Determination of Successful Correction of Breech

As determined by the attending specialist at the time of birth or by ultrasound imaging.

Rates of Management Options

Rates of external cephalic version, planned caesarean section or vaginal birth will be determined for both groups.

Timeline

Initiation: The pilot project is to initialize in January 2003. Prior to commencement, a planned meeting between the chiropractic and medical group will take place to discuss the theoretical and pragmatic issues in carrying out the study.

Duration: The project will continue until equal numbers of patients have been recruited in both groups and all subjects have given birth. If the number of subjects as set forth is not feasible, the pilot project may allow for less number of subjects.

Completion: Both chiropractic and medical investigators will analyze the data and compile the data with the results reported to all parties involved. Dependent on the findings, a more rigorous study (i.e., quasi-experimental or experimental design) may be pursued by all involved.

Statistical analyses

In addition to descriptive statistics, paired t-tests will be used to compare baseline values with comparative post-treatment treatment values. Chi-square analysis will be used for all rate/proportion data. In the event that sample size is limited, then the equivalent non-parametric statistics will be used.

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