

OMT in Labor and Delivery

Running Head: OMT IN LABOR AND DELIVERY

Relationship of Osteopathic Manipulative Treatment
During Labor and Delivery on Selected
Maternal Morbidity Outcomes: A Randomized Controlled Trial

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Dissertation submitted to the Faculty of the
Virginia Polytechnic Institute and State University
in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

in

Education, Curriculum and Instruction

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January 26, 2009
Blacksburg, Virginia

Keywords: maternal morbidity, osteopathic manipulation, OMT, Dominican Republic,
cesarean section, perineal laceration

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(ABSTRACT)

Osteopathic Manipulative Treatment (OMT) has been used for more than 100 years to enhance the physiologic process of labor and delivery by normalizing pelvic structures and providing adequate blood supply to the uterus. Since maternal morbidity and mortality is a major health concern for developing countries, it was desirable to explore the benefits of OMT.

After IRB approval by the Virginia College of Osteopathic Medicine and Virginia Tech, the research was conducted in Santo Domingo, Dominican Republic at Hospital Maternidad Nuestra Señora de la Altagracia to determine the relationship of OMT during labor and delivery on rates of cesarean section and perineal lacerations/ episiotomies. Qualifying candidates received the next sequentially numbered envelope with a randomized number assigning her to either the treatment or control group. Staff physicians at the hospital provided care to women in the control group according to their standard protocol. Four Osteopathic Physicians and one pre-doctoral OMM fellow performed OMT on women during the first and second stages of labor and performed their deliveries.

There were 33 parturients in the OMT Treatment group and 32 in the control, for a total of 65 in the trial. The results of a logistic regression analysis using Wald criterion, with a statistical significance of $\alpha = 0.05$, indicated treatment group reduction of rates of episiotomies in the primiparous ($P = .04$) and marginal significance in the combined primiparous and multiparous population ($P = .05$). The percentage of episiotomies in the primiparous treatment group was 35.29% and 75% in the control group. The percentage of episiotomies in the combined primiparous and multiparous groups were 15.15% in the treatment group and 37.5% in the control group. The cesarean rate for the treatment group was 9.09% and 18.75% for the control group ($P = 0.098$). The percentages of grade I & II perineal lacerations were 15.15% for the treatment group and 12.5% for the control group ($P = 0.55$) due to the extensive use of episiotomies in the control group. There were composite calculations made of the total number of parturients who had either a cesarean section, an episiotomy, or a perineal laceration so that overall maternal morbidity in each group could be compared. In the combined groups, there were fourteen total parturients (42.42%) who had undergone one of the three outcomes measures in the treatment group and twenty-one (65.63%) in the control group. This brings an odds ratio of 0.200 and a significant P value of 0.0235.

Though cross-cultural issues made it difficult to perform the research as originally intended, there is evidence that Osteopathic Obstetrics provides benefit to parturients. A multi-institutional randomized controlled trial is proposed as the next step for the evaluation of OMT during labor and delivery.

Dedication

First and foremost I dedicate this work to God, the masterful Creator of the human body and the intricate processes of labor and delivery.

To my husband Joshua and my son Judah, who were so patient and gracious to support me during this monumental undertaking. I love you more than words can say.

Finally to Anita Showalter, my mentor and Osteopathic Obstetric hero, who first introduced me to the concept of using OMT in Obstetrics. I could not have done this research without you.

Acknowledgements

To my family, both in America and in the Netherlands: thank you for believing in me and encouraging me throughout this challenging process.

To my amazing research team, Dr. Anita Showalter, Brianna Cross, Dr. Aaron Vawter, and Dr. Charlene James: thank you for your hard work, your incredible flexibility, your sense of humor and for never giving up! This research would not have been possible without you.

To the wonderful doctors in the Dominican Republic who made the research a possibility: Dr. Sabado, Dr. Cid, and Dr. Marmolejos.

To our incredible translators who were such a joy to work with: Leslie “Rock Star”, Raymond Capellan and Dr. Abner Saint Gilles.

To my wonderful friends in the Dominican Republic who gave much needed support: Charlie and Darla Finocchiaro, Rich and Kirstin Root, and Aine Clements

To Dr. Sarah Cates, my best friend and comrade in this journey of research: your support and friendship are invaluable to me.

To Dr. Joe Cacioppo, who is such an incredible example of a medical missionary and who has given me so much encouragement through this process.

To my Doctoral Committee: Dr. Sutphin, Dean Tooke-Rawlins, Dr. Redican and John Burton who allowed me to do this study and gave so much support along the way

To Sarah Zalud, who helped me in countless ways.

Last, but certainly not least: to the women of the Dominican Republic: thank you for giving us the honor of performing OMT on you. May your perineums rest in peace, not in pieces.

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Chapter 1

*Introduction**Background*

Approximately two-hundred and ten million women around the world become pregnant each year. Of these, around twenty million will experience pregnancy related illness and 500 000 will die as a result of complications related to childbirth (Neilson, Lavender, Quenby, & Wray, 2003). The World Health Organization (WHO) declared maternal mortality and morbidity a priority and therefore in 1987 they launched the Safe Motherhood Initiative to reduce maternal morbidity and mortality by 50% by the year 2000 (Neilson et al., 2003). They did not succeed, but many strides for improvement have been taken. Cesarean section is primarily the clinical management used to prevent many of the leading causes of maternal and perinatal morbidity and mortality (Holtz & Stanton, 2007).

The latest World Health Organization core health indicators for the Dominican Republic, the location of this research, are as follows: infant mortality rate: 26.0/1000 births (2005), neonatal mortality rate 18/1000 live births (2004), maternal mortality ratio 150/100,000 births (2000), antenatal care coverage - at least one visit 100% (1999), antenatal care coverage – at least four visits 93% (1999), births attended by skilled health personnel 98% (2002), and births by caesarean section 32% (1999) (WHO). Maternal sepsis rates in Latin America is 9.3/100 live births, compared to 0.15/100 live births in the United States (Dolea & Stein, 2000). Unlike other Latin American /Caribbean countries in which Maternal Mortality Rate (MMR) rates have decreased with a high prevalence of institutional delivery, the Dominican Republic has retained relatively high rates of MMR despite high rates of antenatal care and institutionalized deliveries (Miller et al., 2003).

The Dominican Republic has made great strides in providing their expecting mothers with prenatal care and skilled attendance at birth, but the caesarean section rate of 32% and relatively high rates of MMR give cause for concern. The United Nations Population Fund has noted that in the Latin American and the Caribbean areas there has been a 54% increase in cesarean deliveries (Aberdeen, 2004). They remark that a high rate of delivery in institutions does not necessarily mean women are actually receiving good care. Cesarean rates are up to 40% of deliveries in some urban areas. This strongly suggests overuse. Quality of care has thus emerged as a crucial issue (Aberdeen, 2004). The World Health Organization makes the statement that no country is justified in having a caesarean section rate of greater than 10-15% (Chaillet & Dumont, 2007). Cesarean sections, though they are a wonderful life-saving tool, do not come without risk. Cesarean delivery is associated with maternal and neonatal complications and increased costs of health care (Chaillet & Dumont, 2007). Vaginal delivery has been found to be the safest and most cost efficient method of delivery in uncomplicated cases (Byrd, Hobbiss, & Tasker, 2005).

The optimal solution is to normalize and optimize vaginal deliveries. This is the goal of Osteopathic Obstetrics. The founder of Osteopathy, Dr. Andrew Taylor Still had the highest respect for the Creator of the Universe and saw the human body as His handiwork. He gave great attention to the normal anatomy and physiology of the body and used this as the foundation for how he practiced medicine. Osteopathy is “a system of healing which places the chief emphasis on the structural integrity of the body mechanism as being the most important single factor in maintaining the welfare of the organism in health and disease” (Whiting, 1934, p. 532). Allopathic physicians were making birth “pathological and artificial instead of physiological and natural” (Conner, 1928, p. 732). Osteopathy considers birth a normal function of the human body and it

only changes to a pathological condition when the structural phases of the body are neglected (Clark, 1947). Dr. A.T. Still advocated that 90% of births should be normal and should not require a cesarean section or assisted vaginal delivery methods (A. T. Still, 1899).

In comparison with the early 1900s, the percentage of normal deliveries today is much smaller. This presents a researchable question as to why there are a decreased number of normal deliveries, free of cesarean and assisted vaginal methods. Literature in the past has often found that physicians do not allow the labor to progress normally (Beyer, 1941). An osteopathic physician must not be content to let labor take too long or intervene too quickly to introduce artificial means of speeding labor, thereby not allowing the natural progress of child birth (Compton, 1941). An osteopathic approach is to normalize pelvic structures that would allow the child to have a safer journey through the birth canal (Compton, 1941). Osteopathic and allopathic obstetricians are both too-often guilty of interference in the natural process of birth (Quest, 1938).

A definition of the conservative obstetrics that Osteopathic Obstetricians should strive for is: “Meddlesome interference includes unnecessary vaginal examination, episiotomies, forceps, versions and cesarean sections. Meddlesome interference is the antithesis of conservative obstetrics. The recognition at the earliest possible moment of symptoms and signs calling for interference in the interests of mother and child and avoiding, otherwise necessary interference, is the aim of conservative obstetrics” (Foster, 1937, p. 22).

Could it be that the true osteopathic obstetric approach has become pushed aside in our technology-driven society? Little research has been done in recent years about the effects that our osteopathic techniques have on labor and delivery. The case reports from the early 1900’s suggest that OMT helps shorten labor times, decreases perineal tearing,

and decreases use of forceps and therefore suggests these as possible areas for further research. These reports will be covered in greater detail in the Review of Literature.

Maternal morbidity is a major world health problem and one of particular significance in the Dominican Republic. The Edward Via Virginia College of Osteopathic Medicine (VCOM) has a Medical Mission Clinic in collaboration with Secretaria de Estado de Salud Publica y Asistencia Social (SESPAS). VCOM has established medical and academic relationships with the Dominican Government that providing the opportunity to conduct maternal morbidity research and gain formal approval within the hospital and with the Dominican government to conduct research. Further background, theoretical dimensions and related literature on maternal morbidity will be discussed in greater detail in Chapter II.

Problem Statement

High rates of complications associated with vaginal deliveries and high cesarean rates cause short-term and long-term maternal morbidity. Cesarean rates are especially high in Central America.

Purpose of Study

The purpose of this study was to explore the effect of Osteopathic Manipulative Treatment (OMT) during labor and delivery on selected maternal morbidity indicators of rate of cesarean section, perineal laceration and assisted vaginal delivery.

Hypothesis

The null hypothesis was that there would be no difference in the rates of cesarean section, perineal tearing and episiotomies between the treatment and control groups. However, the test hypothesis was that Osteopathic Obstetrics would benefit the normalization of vaginal deliveries with a power of 80% at $\alpha = 0.05$. The outcome

measures were reduction of cesarean section rate, the degree of laceration of the perineum during delivery, and the use of episiotomies.

The hypothesis was tested in a licensed maternity hospital, Hospital Maternidad Nuestra Señora de la Altagracia, with allopathic obstetricians licensed by the Dominican Republic who protected patient health for both the control group and the experimental group receiving OMT. The treatment intervention did not impact the physicians' decision regarding their patients' care.

If the null hypothesis is rejected and OMT is found to reduce cesarean section rates, vaginal lacerations and operative vaginal deliveries from the finding of the study, osteopathic management for normal vaginal deliveries would be an asset to women, particularly those in developing countries where there is limited access to the full range of medical care.

Objectives:

1. Compare the baseline characteristics, including age, maternal weight, gravida, parity, centimeters of dilation on admission, and baby's birth weight between the treatment group and the control groups.
2. Describe the rates of cesarean section, perineal lacerations and episiotomies in Hospital Maternidad Nuestra Señora de la Altagracia in Santo Domingo, Dominican Republic through analysis of the data collected in the control group.
3. Compare the treatment group (OMT) and control group (without OMT) rates on selected maternal morbidity outcome measures of cesarean sections, perineal laceration and episiotomies.
4. Determine the benefits of OMT in labor through objectives 1-3.

Limitations

The findings were limited to the Hospital Maternidad Nuestra Señora de la Altagracia and the standard of care provided by the five osteopathic physicians who performed all of the OMT for the parturients. There were also limitations on the generalization of findings to the five practicing physicians. The limited number of women in this study, along with the particular set of characteristics associated with their cases were also limiting factors. Physicians attending the control group represent limitations according to their training, professional views of medical applications to the cases and other characteristics unique to them. While there may be inferences to other settings that have similar characteristics and implications for additional research, caution should be exercised to avoid extrapolating the data in inappropriate ways.

Definition of Terms

Abnormal placentation – the implantation of the placenta in a suboptimal position of the uterus.

Antenatal care – medical care given to a pregnant woman throughout gestation by a licensed professional; synonym for prenatal care.

Cesarean section - delivery of the baby through a surgical incision in the mother's abdomen and uterus.

Core health indicators – statistics that show the level of health care that a country receives.

Episiotomy – incisions in the perineum made by the obstetrician to aid in the delivery of the baby. They can either be midline, an incision straight towards the rectum, or mediolateral, an incision that is made at a 45-degree angle to midline.

Fetal malpresentation – a suboptimal fetal position for childbirth.

First stage of labor – the dilation of the cervix from one to ten centimeters.

Instrumental vaginal delivery – deliveries that use forceps or vacuum to assist the baby into extra uterine life.

Maternal mortality – death of a woman while she is pregnant or shortly after parturition.

Maternal morbidity – any disease or non-physiologic function incurred as a result of childbirth.

Maternal mortality ratio – the number of maternal deaths per 100,000 live births.

Multiparous – the parturient has had at least one baby before the current pregnancy.

Multiple gestation – more than one fetus in one uterus.

Non-reassuring fetal status – indications that the fetus is in distress.

Osteopathic Manipulative Treatment (OMT) – using the hands to diagnose, treat or prevent illness or injury.

Osteopathic obstetrics – the practice of obstetrics that adheres to the tenants of osteopathy; views labor as a natural process.

Pelvic organ prolapse – the prolapse of the pelvic organs through the vaginal orifice to varying degrees.

Perineal laceration – tearing of the perineum during delivery of a baby, rated from first to third degrees. First-degree lacerations only involve injury to the perineal skin and vaginal epithelium. There is no disruption of the perineal muscles. In second-degree lacerations the injury extends into the fascia and the perineal, pubococcygeus and bulbocavernosus muscles, but the anal sphincter is intact. Third degree lacerations also have injury to the above structures as well as extending into the fibers of the external anal sphincter and /or the internal anal sphincter.

Perinatal morbidity – any disease on non-physiologic state incurred by a baby just before, during or after childbirth.

Perinatal mortality – any death of a baby just before, during or after childbirth.

Prenatal care – medical care given to a pregnant woman throughout gestation by a licensed professional; synonym for antenatal care.

Primiparous – the parturient is having her first baby.

Primary cesarean section – the first cesarean section a woman undergoes.

Puerperal sepsis – a general term to describe any infection of the genital tract after delivery.

Randomized controlled trial – a study that randomly assigns individuals to an intervention group or to a control group, in order to measure the effects of the intervention.

Repeat cesarean section – the woman has undergone at least one previous cesarean section.

Second stage of labor – the time from the complete dilation of the cervix to delivery of the baby.

Secretaria de Estado de Salud Publica y Asistencia Social (SESPAS) – public health service provided by the government of the Dominican Republic.

Sham OMT – Positional changes with the operators hands without applied osteopathic treatment.

Standard treatment during labor and delivery – guidelines set by the Hospital Maternidad Nuestra Señora de la Altagracia for treatment during labor and delivery to assure standard of care.

Third stage of labor – delivery of the placenta.

Uterine rupture – the tearing of the uterus during pregnancy.

Vaginal birth after cesarean delivery (VBAC) – a vaginal delivery accomplished after a woman has had a cesarean section.

Vesico-vaginal fistula – an opening between the bladder and the vagina that causes a constant leaking of urine.

Significance

Maternal mortality and morbidity is of incredible importance worldwide. The World Health Organization and many other organizations make it a matter of great priority. There are clear links between increased rates of cesarean section and episiotomies and maternal sepsis. If the use of OMT during labor and delivery can reduce the numbers of cesarean section and episiotomy via the optimization of the vaginal delivery there would be tremendous benefit. There are limited studies on the impact that OMT has on maternal morbidity. This study will provide groundbreaking research on OMT during labor and delivery.

In addition, collaboration between U.S. and Dominican doctors in the controlled research setting will be explored as a result of the planned activities. This offers an additional benefit and insight into the potential for future research and collaboration in the practice of medicine. Areas of difficulty can be potentially reduced in future studies as a result of experience in this study.

Lastly, this study contributes to the limited research-based literature on Osteopathic medicine. If there is evidence from this study that Osteopathic techniques during childbirth are successful and with additional study, medical practices could be changed to benefit care provided during childbirth.

Chapter 2

Review of Literature

Introduction

This review of literature analyzes the current rates, reasons and risks of cesarean deliveries, instrumental vaginal deliveries and perineal laceration during delivery. These are the three major outcomes that will be examined in this study along with a thorough explanation of the topics. The Review of Literature will then cover previous studies of Osteopathic Medicine in obstetrics, the benefits that OMT provides according to the literature and the mechanisms of osteopathic manipulation.

Cesarean Delivery

A cesarean delivery is the delivery of the baby through a surgical incision in the mother's abdomen and uterus. The first cesarean delivery for the woman it is termed "primary". If the woman has had a previous cesarean it is termed "repeat".

In developing countries the urban rates of Cesarean delivery are up to four times that of the rural rates (Holtz & Stanton, 2007). One might therefore see over- and under-use of cesarean deliveries in the same country. The United Nations has promoted the use of cesarean birth rates as an indicator of access to emergency care (Holtz & Stanton, 2007). They claim that the rates of cesarean section should be between 5 and 15% is important data that every country should monitor (Holtz & Stanton, 2007). The worldwide rate of cesarean delivery is 15% (Betran et al., 2007). Latin America and the Caribbean have the highest rates of cesarean delivery in the world at 29.2% (Ronsmans, Holz, & Stanton, 2006), except for the United States which is topping the scales at 30.2% (cdc.gov). The cesarean rate in private hospitals in developing countries tends to be very high. The wealthiest 10% of Brazilian women have a cesarean delivery rate of 77% (Ronsmans et al., 2006).

Demographic and health surveys (DHS) provide the most accurate, up to date, and accessible information about cesarean birth data. The first DHS for the Dominican Republic was in 1991. It reported a 22.0% cesarean birth rate. The most recent DHS for the Dominican Republic in 2002 reported a 33.5% rate (Holtz & Stanton, 2007). This is an alarming increase. This creates great concern because the rates of perinatal morbidity and mortality are not decreasing (Neilson et al., 2003).

The main indications of cesarean delivery are failure to progress during labor (30%), previous hysterotomy (usually cesarean delivery) (30%), nonreassuring fetal status (10%) and fetal malpresentation (11%). These constitute 80% of Cesarean deliveries (Capeless & Damron, 2007). Other causes are abnormal placentation, maternal infection, multiple gestation, fetal bleeding diathesis, and mechanical obstruction of birth canal (Capeless & Damron, 2007). Each of these issues can lead to potential harm or death of mother or baby. For example, failure to progress during labor can lead to vesico-vaginal fistulas, which cause an opening between the bladder and the vagina. "Vesico-vaginal fistulas mainly result from the ischemic necrosis of vaginal and bladder tissues, trapped between the fetal head and the mother's pubic symphysis during prolonged, obstructed labor (Neilson et al., 2003). This causes a constant leaking of urine, which causes devastating social, psychological and physical harm to the mother (Ezegwui & Nwogu-Ikojo, 2005). Approximately 90% of genito-urinary fistulas are a result of prolonged or obstructed labor in developing countries without access to proper emergent obstetrical care (Wai & White, 2006). The World Health Organization defines prolonged labor as any time greater than eighteen hours for a primagravid woman (woman delivering her first child) (Neilson et al., 2003).

Cesarean delivery has its place and does provide great assistance; however its overuse also carries risks to both mother and baby. There are general risks of surgery to

be considered, including bleeding, the need for a blood transfusion, damage to internal organs, infection, and deep vein thrombosis (Dodd & Crowther, 2007). There is a growing amount of evidence that suggests that the single most important risk factor for postpartum infection is cesarean section (Dolea & Stein, 2000). Postpartum infection can lead to sepsis and is a significant source of maternal morbidity and mortality in developing countries. These infections can also lead to infertility if the woman survives the infection, which further contributes to the morbidity associated with cesarean deliveries (Dolea & Stein, 2000). Cesarean deliveries also carry the risk of future uterine rupture, which causes devastating maternal and neonatal morbidity and mortality worldwide (Turner, Agnew, & Langan, 2006). The focus of attempts to decrease the rates of uterine rupture center around decreasing primary cesarean rates ("WHO systematic review of maternal mortality and morbidity: the prevalence of uterine rupture," 2005). There is also a small but significant risk of urogenital fistulas associated with Cesarean delivery due to injury to the bladder (Rao et al., 2006; Wai & White, 2006). There are increased complications with multiple repeat Cesarean deliveries (Rashid & Rashid, 2004). The abdomen is more difficult to dissect and it is more difficult to separate the bladder from the lower uterine segment (Rashid & Rashid, 2004). There is increasing evidence that multiple Cesarean deliveries cause abnormal placentation, that is, the placenta will assume a suboptimal position on the uterine wall due to scarring (Ananth, Smulian, & Vintzileos, 2003). Babies born by Cesarean delivery were found to have a three times higher rate of respiratory morbidity (Levine, Ghai, Barton, & Strom, 2001; Many et al., 2006; Turner et al., 2006). It is thought that the mechanism of labor promotes neonatal respiratory function and the expulsion of fluid from the fetal lungs (Many et al., 2006).

Vaginal birth after cesarean delivery (VBAC) is a safe, viable option for many women and is an excellent way to decrease the Cesarean birth rate (Loebel, Turner, 2004). In women with one low transverse cesarean delivery, certain provisions must be met during vaginal birth after cesarean section in order to achieve optimal safety of mother and baby. These provisions include: avoidance of induction of labor unless clinically necessary, close supervision of labor, oxytocin usage only by experienced clinicians, and the immediate availability of surgery (Turner et al., 2006). The literature indicates that the success of a VBAC was greatly increased if the mother had had a previous vaginal delivery (Dodd & Crowther, 2007; Turner et al., 2006).

Instrumental Vaginal Deliveries

Instrumental vaginal deliveries are those that use forceps or vacuum to assist the baby to delivery. The indications for instrumental vaginal deliveries, as outlined by the American College of Obstetricians and Gynecologists are prolonged second stage of labor, suspected imminent fetal compromise when vaginal delivery is close at hand, and maternal benefit in shortening the second stage (ACOG, 2000). ACOG defines prolonged second stage in primiparous women as no progress for three hours with spinal anesthesia and two hours without. In multiparous women it is defined as no progress for two hours with spinal anesthesia and one hour without (ACOG, 2000). Shortening labor for maternal benefit has fallen out of favor in the literature because of the morbidity related to the use of instrumentation, especially forceps (Yancey, Herpolsheimer, Jordan, & Bradley, 1991).

Immediate maternal risks of instrumental delivery include pain, lacerations to the lower genital tract, hematomas and urinary retention (Liu et al., 2005). Long-term consequences of instrumental delivery are urinary incontinence, fecal incontinence and

pelvic organ prolapse due to injury of the pelvic floor (Byrd et al., 2005; MacArthur, Bick, & Keighley, 1997; Varma, Gunn, Lindow, & Duthie, 1999).

Fetal risks are related to the compression of the head, traction to the intracranial structure, face and scalp, and lacerations (Towner, Castro, Eby-Wilkens, & Gilbert, 1999). These injuries can lead to intracranial hemorrhage and neuromuscular injury, but long-term risk of these injuries is usually small (Wegner & Bernstein, 2007).

Perineal Lacerations and Episiotomies

Perineal lacerations can be classified in three degrees. The definitions used here will be according to the one Sultan proposed in 1999 (Sultan, 1999). First-degree lacerations only involve injury to the perineal skin and vaginal epithelium. There is no disruption of the perineal muscles. In second-degree lacerations the injury extends into the fascia and the perineal, pubococcygeus and bulbocavernosus muscles, but the anal sphincter is intact. Third degree lacerations also have injury to the above structures as well as extending into the fibers of the external anal sphincter and /or the internal anal sphincter. There are sub-classifications of third degree lacerations. “Three A” has less than 50% thickness laceration to the external anal sphincter; “three B” has greater than 50% thickness laceration of the external anal sphincter; and “three C” has laceration of the internal anal sphincter as well as the external anal sphincter. Fourth degree lacerations involve all of the above structures as well as rectal mucosa (Sultan, 1999).

Episiotomies are incisions made by the obstetrician to aid in the delivery of the baby. They can either be midline, an incision straight towards the rectum, or mediolateral, an incision that is made at a 45-degree angle to midline.

Perineal lacerations are common and one author reported rates of 85% in women undergoing normal vaginal delivery (Premkumar, 2005). Third and fourth degree

lacerations have much more associated morbidity and have rates of 0.5 – 6% of vaginal births (Thornton & Lubowski, 2006).

Risk factors for sustaining a third or fourth degree laceration are vaginal delivery, instrumental delivery (especially forceps), episiotomy, breech or mal presentation of the fetal head, primiparity, birth weight above 4 kg, prolonged second stage, and gestational age greater than 42 weeks (Byrd et al., 2005; Elfaghi, Johansson-Ernste, & Rydhstroem, 2004; Thornton & Lubowski, 2006). Position was also found to affect the risk of perineal trauma. The traditional lithotomy position increases the risk for episiotomy (Premkumar, 2005) and the lateral (side-lying) position has been shown to be associated with less perineal trauma (Byrd et al., 2005). This damage to the perineal floor can carry significant morbidity for the mother. Sixty percent of women who have a third or fourth degree laceration suffer with fecal incontinence, dyspareunia, or pelvic pain (Byrd et al., 2005). As a result of the disruption of the pelvic muscles and facial support, women can also suffer from pelvic organ prolapse and urinary incontinence (Thornton & Lubowski, 2006).

It is these complications, which cause women to elect for a cesarean section instead of risking damage to their pelvic floor and anal sphincter. In fact, in a survey of female obstetricians in the United Kingdom, 31% would opt for a cesarean delivery even in the case of a normal, uncomplicated vaginal delivery. Eighty percent of them would choose cesarean delivery because of fear of a sphincter injury. If there was a risk factor involved, such as forceps, then the percentage opting for cesarean rose to 68% (Thornton & Lubowski, 2006). This thinking is becoming more and more prevalent, which is why many of the affluent private patients are opting for cesarean section. However, very large numbers of cesarean sections would have to be performed in order to prevent a small number of sphincter tears (Byrd et al., 2005). Also, Cesarean delivery does not guarantee

that a woman will avoid pelvic floor damage. As previously discussed, cesarean sections are not without risks of their own, not to mention the tremendous economic burden to the health care system. One of the potential solutions to this problem lies in making vaginal deliveries safer and more common, with less risk of injury and therefore fewer complications.

Another serious complication of having an episiotomy, especially in a developing country is the risk of infection. There is an alarming rise in the rates of Methicillin Resistant Staphylococcus aureus (MRSA) in postpartum patients (Asnis, Haralambou, & Tawiah, 2007). These are dangerous infections because of the difficulty of treating the multi-drug resistant strain of bacteria. MRSA is a community-associated infection that usually causes soft tissue infection (Rotas, McCalla, Liu, & Minkoff, 2007). If it is not detected quickly it can lead to maternal sepsis and death (Rotas et al., 2007). This represents an especially large problem in developing countries where many risk factors increase the occurrence of these puerperal infections. Some of these risk factors include: poor access to clean water to properly care for episiotomy sites, poor access to postnatal care, and lack of knowledge regarding signs and symptoms of puerperal infection (Dolea & Stein, 2000). There is a clear link between the high cesarean rates and high episiotomy rates and the high rates of maternal sepsis in developing countries (Dolea & Stein, 2000).

Osteopathic Literature Related to Obstetrics

There are not many previous studies dealing with Osteopathic Manipulative Treatment (OMT) and labor and delivery. Most of the literature from the early 1900's included case reports and information about OMT techniques in pregnancy, labor and delivery, and the postpartum period. Some authors did have studies on a larger scale. Whiting, in 1934, reports examining 500 of her cases. She found that time of her laboring patients were one half the current published times of 18-24 for primiparas and 12 hours

for multiparas (Whiting, 1934). There was an obstetrical report compiled in 1932 by S.V. Robuck, DO, a member of the Clinical Research Committee of the A.T. Still Research Institute. It cited 13, 816 women who received prenatal OMT and were delivered by osteopathic physicians. Of those, “thirty mothers died, which is a mortality rate of 2.2 per thousand living births, compared with 6.8 per thousand rate in Caucasian mothers quoted from government bulletins” (Jones, 1933; King et al., 2003). Guthrie and Martin sampled 500 laboring women and found that 352 had severe lumbar pain related to abnormal fetal position. They used OMT on the lumbar area in the study group and OMT in the thoracic area in the control group to see if OMT had an effect on the pain. They found that there was a marked decrease in pain in the lumbar OMT group as compared to the thoracic group (Guthrie & Martin, 1982). King et al. did a pilot study looking at labor and delivery outcomes in women who had prenatal OMT, compared to women who had not. Prenatal OMT was strongly associated with decreased numbers of preterm delivery and meconium-stained amniotic fluid. While the women in this study will not have the benefit of prenatal OMT, it is encouraging to see the benefit of OMT.

The Foundations for Osteopathic Medicine textbook has an excellent chapter on Obstetrics. It emphasizes the need for an osteopathic structural exam on the laboring patient with emphasis on the lumbosacral spine and pelvis, and mobility of the sacrum (Ward, 2002). The thoracic and lumbar spine should also be gently treated with soft tissue or muscle techniques to enhance uterine contractions through sympathetic innervation (Ward, 2002). There is also evidence that treatment of any dysfunction in the sacral base may aid cervical dilation (Ward, 2002). Correcting dysfunction in the pelvis is of paramount importance to a laboring woman. It may assist labor and the birth process by creating more movement and room in the pelvis, allowing the fetal head to traverse more easily (Ward, 2002). The current study provides a research base for these

conceptual assertions by establishing the correlation between use of OMT during labor and delivery and decreased morbidity for the mother.

Historical Benefits of OMT

Historically, the osteopathic literature makes remarkable claims regarding the impact that OMT has on labor, delivery and postpartum recovery. These are drawn from case reports and general experiences of the physicians, rather than the larger studies above, but they are still useful in establishing a basis for the efficacy of OMT.

The basis for obstetric osteopathic philosophy is that labor is a natural process, that we assist by physiologic means (C. E. Still, 1900). Still's philosophy was that the knowledgeable student should be able to utilize the knowledge of labor mechanics to assist the laboring mother without resorting to instrumentation. "The osteopath always works in harmony with Nature along common sense lines" (Gilmour, 1904, p. 440). An osteopath makes a labor and delivery more "normal" by lessening the time and pain that a woman has to endure and by making the delivery safer for mother and baby (Grow, 1933; Lorenz, 1917).

Part of this normality involves timing. "The first great rule in a successful obstetrical practice is: don't be in a hurry to get through" (Betts & Huron, 1921, p. 85). One doctor noted that speed of labor and delivery took precedence over safety (Quest, 1938). This should never be. One must wait until the woman's body is ready to embark on the process of labor and delivery. "I think 90% of difficult labors come from not waiting until the fullness of time. I believe many false pains are stimulated into true pains, resulting in a long, hard labor, ending in a forceps delivery, a lacerated mother, and perhaps a dead or maimed baby" (Conner, 1928, p. 853). This being said, there is an abundance of references to osteopathy leading to a significantly shorter labor and delivery process using natural means. Some claims are that labor will be shortened by

one half with proper treatment (Cooper, 1921); that labor with an osteopathic physician is seven to nine hours shorter than those with an allopath (Lorenz, 1917); that the average time to delivery from the beginning of contractions is three hours for a primipara and one and a half hours for a multipara (C. E. Still, 1900). It is interesting to note that while emphasis is placed on normalizing labor, osteopathic techniques that work with physiologic labor serve to significantly shorten the labor according to the case reports. While length of labor and delivery is not one of the research variables in this study, prolonged labor is one of the most frequent reasons for a cesarean section, use of forceps and lacerations. Having a short, normal labor will avoid much maternal morbidity.

Instrumental deliveries of the early twentieth century, when most of these case reports were written only used forceps; there were no vacuum devices to assist with delivery. Osteopathic physicians had much to say about the use of forceps. “Forceps may be necessary once in a thousand times . . . it is the ignorant physician who is most eager to use instruments” (Musick, 1899, p. 327). “If one cannot devote the necessary time and give the mother a fair chance without the premature use of forceps and abuse of pituitin he has no place in the practice of obstetrics” (Leonard, n.d., p. 10). Forceps do play an important role in assisting in delivery to ensure safety of the child in some instances, but their overuse should be avoided. An osteopathic physician simply finds that it is not necessary to use such a tool when physics of the woman’s body are optimized for the baby’s departure.

Preventing lacerations were of prime importance to osteopathy’s founder, Dr. A.T. Still. He said when principles of osteopathy are utilized, “laceration may occur in one out of a thousand cases, and you will be to blame for that one, and may be censured for criminal ignorance” (A. T. Still, 1899, p. 241). Many authors talk about osteopathic obstetrics preventing lacerations to the cervix and the perineum (Conner, 1928; Overfelt,

1915; Quest, 1938; C. E. Still, 1900). When lacerations of the perineum are avoided, the pelvic floor remains intact and the risk of pelvic organ prolapse, and urinary and fecal incontinence are at a minimum (Quest, 1938; C. E. Still, 1900).

Physiologic Mechanisms of OMT

The reported benefits seem almost too good to be true. It is important that we dedicate a section of the Review of Literature to provide the physiologic framework for why osteopathic techniques work. Osteopathy's core is the study of anatomy and physiology. These are the basis of the practice of osteopathic obstetrics (Whiting, 1934, 1945). It is these concepts that provide the foundation for the actual osteopathic techniques that will be presented in the methods section. "Bones, muscles, blood and nerves are all important to the osteopathic physician, but especially must he understand the great nervous system, for in such knowledge lies his strength. We know there are certain nerve centers which control certain parts, and to so act upon those centers that they may do the work required, is the province of the osteopath." (E. M. Still, n.d., p. 203) The primary sympathetic innervation for the uterus is derived from nerves at the Thoracic 10-12 and Lumbar 1-2 spinal levels. These are mainly pain fibers. The primary parasympathetic innervation is derived from the Sacral levels 2-4. These are mostly motor (Ward, 2002). Therefore most of the osteopathic treatments for labor and delivery are oriented towards these spinal levels. Any interference in the nervous control of the uterus will disturb the efficiency with which the uterus contracts. Women with abnormal uterine contractions often have dysfunctions affecting the lower thoracic and upper lumbar segments (Ward, 2002; Whiting, 1945). Inertia of the uterus rarely occurs when there is adequate innervation of the uterine muscles (Whiting, 1945).

The uterus is arranged in three layers of muscles: longitudinal, oblique and circular. The longitudinal form the greatest part of the uterine fundus and are the most

important in the expulsion of the fetus. The circular are mostly located in the cervix. These are the muscles responsible for regulating the size of the opening of the cervix. These are controlled, as mentioned above by the sympathetic nerve sources. An osteopathic physician can assist in the contraction of the fundus by stimulation of the lumbar spine and the relaxation of the cervix by treating the sacral base (Smith, n.d.; C. E. Still, 1900; Ward, 2002).

While the adequacy of nervous innervation can affect muscles (like the uterus), it can also affect blood supply. A contracture of muscle in the lumbar region that affects the nervous innervation to the sympathetic uterine plexus can cause a vaso-constrictive action on the uterine vessels (Smith, n.d.; Ward, 2002). Therefore the uterus, which needs all the blood it can get to power its contractions, has an impaired blood supply and this may cause inadequate contractions and fatigue of the uterus

A major cornerstone of osteopathic technique is proper positioning of the mother so that the birth canal will be as straight and short as possible (Conner, 1928). To illustrate this point, Dr. Still gave an allegory of a farmer driving a wagon through a fence. If the wagon passed through at right angles, it would have not have any difficulty passing through. However, even if you have a 10-foot clearance for a seven-foot wagon and tried to pass it through an angle you could easily cause damage. In the same way, a baby will pass more easily through a straight tube than a crooked one. The goal is to position the mother so that the baby will strike the birth canal at right angles (Conner, 1928). A woman who lies on her back has a crooked birth canal. The birth canal is much straighter if the woman squats or assumes a side-lying position (Whiting, 1945).

Positioning is part of the secret for preventing lacerations. Also, it is important to make sure that all parts of the cervix dilate at the same time. Because of positioning, the fetus should be central and should not rest against one lip all of the time, therefore there

should be no laceration (C. E. Still, 1908). In precipitous deliveries, the osteopathic physicians should slow the delivery of the head until tissues are sufficiently relaxed to prevent tearing (C. E. Still, 1900). With these keys in mind, osteopathic physicians propose that most lacerations are preventable.

Summary

The review of literature provides evidence to support further investigation and the directional hypothesis that OMT has the potential to reduce maternal morbidity and the criterion measures of cesarean section, instrumental deliveries, and perineal lacerations for this study. This is especially evident in view of the high rates of maternal sepsis in the Dominican Republic and its association with cesarean sections and the use of episiotomies.

While there are limited studies on the effect of OMT on maternal morbidity, there is substantial research on maternal morbidity in clinical and research settings. These studies are useful to the current research in that they provide a framework for establishing the widespread problem of maternal morbidity.

The literature has important background and basis for the research methodology for this study in terms of the general and to an extent specific benefit. However, there are limited studies on maternal morbidity related to OMT and none were found of particular relevance in third world settings. This study builds on the work of Dr. King, et al. who researched the effects of prenatal OMT. This OMT research during labor and delivery is a pioneering effort, based on substantial clinical and anecdotal evidence of the potential for benefits regarding the criteria tested in this study.

Chapter 3

*Methods**Introduction*

This study was a randomized controlled trial in which the techniques of Osteopathic Manipulation (OMT) during labor and delivery were compared with the standard treatment. Method of randomization and allocation concealment were as follows: a Statistical Analyst generated the randomization sequence that was transferred to cards and subsequently placed into sequentially numbered opaque envelopes. Participants who met the eligibility criteria and also offered informed consent were assigned to one of the treatment arms by opening the next envelope in the sequence. There was no sham OMT performed due to lack of feasibility in the trial. The outcomes are quantitative, not qualitative. These techniques controlled for bias due to the lack of sham OMT. The study took place in Hospital Maternidad Nuestra Señora de la Altagracia, a maternity hospital in Santo Domingo, Dominican Republic. There were reported to be approximately seventy deliveries per day at this hospital, which made it a desirable setting for this study.

Randomized Controlled Trial

There are guidelines set for Randomized Controlled Trials. The CONSORT statement is an authoritative guideline for reporting randomized controlled trials. It involves flowcharts and checklists to ensure that all of the elements are adequately performed and reported (Moher, Schulz, & Altman, 2001). In the methods section it outlines participants, interventions, objectives, outcomes, sample size, randomization: sequence generation, allocation concealment, implementation, blinding (if appropriate) and statistical methods (Moher et al., 2001). “The strength of the randomized trial is based on aspects of design which eliminate various types of bias” (Altman & Schulz,

2001, p. 446). This involves randomization of patients to treatment groups and concealing the allocation sequence (Altman & Schulz, 2001). These are essential features of randomized controlled trial. Great care has been taken to ensure that this trial was carefully randomized with a computer generated number sequence generated by an experienced statistical analyst and the sequence was concealed until after the participants were enrolled in sequentially numbered sealed opaque envelopes. The use of sequentially numbered, sealed opaque envelopes are supported in the literature as a reliable method of concealing the allocation sequence (Altman & Schulz, 2001). The guidelines set for a randomized controlled trial as outlined in the CONSORT statement were carefully followed in this randomized controlled trial.

Osteopathic Team

The osteopathic team was comprised of the author, Dr. Amy Keurentjes, DO, PhD candidate; Dr. Anita Showalter, DO, board member of the American College of Osteopathic Obstetricians and Gynecologists and head of the division of Obstetrics and Gynecology at the Pacific Northwest University of Health Sciences; Dr. Charlene James, DO, PhD, Family practice; Dr. Aaron Vawter, DO, Family practice resident; and Brianna Cross, MSIV, OMM Fellow at Touro University. The Osteopathic team received detailed training from the researcher on the specific techniques to be utilized in the study before the research began to assure inter-rater reliability.

Population and Sampling

The inclusion criteria are women who were admitted for labor during the study dates with a singleton, vertex fetus and had obtained at least 34 weeks gestation. The exclusion criteria included factors known to be contraindications for vaginal delivery and factors that significantly increase risk for cesarean section. Contraindications for vaginal delivery are a prior cesarean with a vertical incision, more than one cesarean with a

transverse incision, non-vertex fetal position, and multiple gestation. Factors increasing risk of cesarean section are gestational diabetes, gestational hypertension, preeclampsia, eclampsia and more than one prior cesarean section. Women presenting with these contraindications and factors that increase risk for cesarean were excluded. Women under the age of 15 and over the age of 40 were also excluded. Parturients filled out eligibility criteria sheets, included in Appendix C, upon their admission to the hospital. Any woman not meeting criteria was not entered in the study, but their eligibility criteria sheet was retained until their reason for exclusion was recorded. The record will be destroyed to protect confidentiality.

A randomized and allocation concealment technique was utilized. A statistical analyst generated the randomization sequence that was transferred onto cards and subsequently placed into opaque envelopes. Parturients who met the eligibility criteria and also offered informed consent were assigned to the treatment or control group by opening the next envelope in the sequence. The staff physicians at the hospital managed the women in the control arm in the usual manner. The staff physicians provided medical care to the women in the control group according to the standard protocol. The staff physicians were mostly Obstetrics and Gynecology residents who were overseen by a Dominican attending physician.

The Osteopathic Physicians performed OMT on women in the treatment group during labor and performed their deliveries. However, the staff physicians still made the decisions that controlled the course of their care. For example, the staff physicians in the Dominican Republic were the ones who made the decision to take parturients in the treatment group to cesarean section.

Based on the inclusion criteria, there were thirty-three women in the treatment group and thirty-two women in the control group. Sixty-six women were excluded from the study based on the exclusion criteria detailed above.

Power Analysis

A power analysis using the PASS System (NCSS, Kaysville, UT) showed that at least 372 participants would be required to detect an odds ratio of 0.5 for the association between OMT treatment and CSD with a power of 80% at $\alpha = 0.05$. Furthermore, the sample size calculation assumed a 50% allocation ratio of participants between the 2 groups (Treatment vs. Control), and a 30% baseline prevalence of CSD in the Dominican Republic. The duration of the study was six days. It was assumed that sixty of the seventy parturients each day would qualify and would be willing to participate in the study.

The actual numbers of women entering the hospital in labor were markedly lower than expected and a larger than the anticipated percentage had to be excluded due to previous cesarean sections and pregnancy-induced hypertension. While the number of women included in the population and sample as described in the previous section did not match the power test, the numbers were adequate for this pilot study to develop baseline data. Future studies will benefit from the lessons learned in this study to build a design and length of time to accommodate the full measure of the power test.

Data were analyzed using logistic regression and a 2 sample T test and Fisher's exact test were also utilized. Selection of the statistic was based on the individual objectives and level of data, whether nominal, ordinal or interval.

Instrumentation

Instruments were researcher developed based on the review of literature and experts who assisted in the study. Content validity was established by using a panel of experts who were given a copy of the research purpose, objectives and strategies along

with a key to show the data aligned with each objective. The panel consisted of the physicians conducting the Osteopathic Manipulative Treatment and panel members representing statistical expertise, education and indigenous knowledge of the culture. Based on this review, the panel of experts concluded the instruments were valid measures of the research objectives. Since the instrument did not have interval level scales, there was not a need to develop reliability coefficients.

After development, each instrument was coded to protect individual anonymity. The woman's name was recorded in a code book, and assigned a numeric identifier recorded on the instrument. Data were entered into the researcher's password protected computer using the numeric identifier for each instrument. The code book with the individual's name and identifier was kept separate and in a secured area. Data were entered into the computer for the dependent and independent variables so that they could be appropriately compared in the analysis after the research to minimize confounding factors. These independent variables are as follows: age, maternal weight, gravida, parity, cervical centimeters of dilation on admission, and the baby's weight. The staff physicians participated in recording the data for the control group, and the osteopathic physicians recorded the data in the treatment group. A sample page of the log can be found in Appendix C.

Data Collection

The staff physicians at Hospital Maternidad Nuestra Señora de la Altagracia collected the data on the control group by using the data collection sheets provided. The osteopathic physicians collected the data on the treatment group on their data collection sheets. All involved in data collection received training by the researcher to control for inter-rater reliability. All data were collected just after the baby was delivered. The Osteopathic physicians also recorded OMT performed during labor. All data were highly

secured under lock and key in both the Dominican Republic and the United States. All information that was entered into the researcher's computer was protected by a password. The study results were not a part of the patient's medical record.

Procedures

Once the women who entered the hospital were determined, per hospital protocol, to be in active labor, they were randomly assigned to the control or treatment groups as previously defined. The control group received exclusive care by the staff physicians of Hospital Maternidad Nuestra Señora de la Altagracia using the usual guidelines for labor set by the hospital. The women in the treatment group were also followed by the staff physicians, but additionally received Osteopathic Manipulative Treatment during the first and second stages of labor by the Osteopathic physicians. The Osteopathic team also performed the vaginal deliveries in the treatment group and repaired any lacerations that occurred. The Dominican staff physicians made all of the decisions regarding the care of both groups and thus made any decision regarding cesarean section. The Dominican staff physicians performed the cesarean sections needed by women in the treatment group.

The study extended for six days. During this time there was coverage of the treatment group by at least one of the Osteopathic physicians. This was accomplished using a rotating schedule for the osteopathic physicians. The Dominican staff physicians covered the control group in the usual manner.

Written informed consent was provided in Spanish and located in the Appendix A of this document. IRB approval was obtained prior to this study through the Virginia College of Osteopathic Medicine and Virginia Tech. The staff physicians practicing at the hospital also approved the proposal before the study was initiated. Utmost care was taken to ensure that women in both groups received the standard of care and privacy.

The methods of OMT were based on the osteopathic literature found in the review of literature. Great effort has been made to be true to the pure roots of osteopathic obstetrics, which was presented in the review of literature.

The women in the treatment group had an initial physical examination by an osteopathic physician. This involved an osteopathic evaluation to determine if there was a musculoskeletal dysfunction that could interfere with normal delivery.

Examination emphasized the pelvis, but also involved the thoracic and lumbar regions. The pelvis was examined to reveal any sacroiliac or lumbosacral dysfunction. These dysfunctions could interfere with the passage of the fetus. The mobility of the sacrum is particularly important for a laboring woman (Ward, 2002). If such a dysfunction was found, then it was corrected using muscle energy techniques. The specific muscle energy technique was chosen according to the problem that was found in keeping with the principles of osteopathy. One of the most common techniques utilized by the team was Dr. Eberly's Figure of Four. In this treatment for an anterior innominate, the thenar eminence of the examiner's hand was placed on the patient's low anterior superior iliac spine and concurrently the other hand put downward force on the opposite knee that is bent to the side (like a number four). The patient is then asked to straighten their bent leg. While they are straightening, the examiner puts cephalad force on the low anterior superior iliac spine. This gaps the pubic symphysis and allows the low anterior superior iliac spine to return to its physiologic position. Other examples of muscle energy techniques used in the study are in Appendix B.

Attention was then turned to the thoracic and lumbar spine. The entire spinal musculature was then relaxed using gentle soft tissue techniques, with concentration on the lower thoracic and lumbar segments (Ward, 2002). If any dysfunctions were found, they were also corrected using the muscle energy techniques as portrayed in Appendix B.

Concentrating on these segments stimulates the uterine blood flow and promotes strong, effective uterine contractions via sympathetic influence (Ward, 2002). The examination and initial osteopathic treatments took place in the first stage of labor. The first stage of labor involves the dilation of the cervix to ten centimeters. The parturients were encouraged to walk or to change position every twenty to thirty minutes in the first stage of labor. She was also encouraged to squat periodically and the osteopathic physicians performed sacral rocking, both of which help the fetal head descend. Treatment of the sacral base may also enhance cervical dilation (Ward, 2002).

Dilation should proceed at least one centimeter per hour (Funai & Norwitz, 2007a) and contractions should occur three to five times in ten minutes for adequate labor (Funai & Norwitz, 2007b). Slow progress is most often the result of inefficient uterine action (Frigoletto, 2007).

If a parturient in the treatment group did not progress by one centimeter an hour then a stimulatory technique for lower thoracic and upper lumbar was given to counteract uterine dystocia. This took place with the woman in a sitting position and the physician using a percussive technique to the lumbar paraspinals for one to two minutes every fifteen minutes. The parturients received amniotomies and pitocin at the discretion of the Dominican staff physicians.

The second stage of labor is the “interval between full cervical dilation (10 centimeters) and delivery of the infant” (Funai & Norwitz, 2007b, p. 3). It is divided into two phases. The first phase starts at full cervical dilation and lasts until the fetal head reaches the pelvic floor (Frigoletto, 2007). The second stage starts when the head reaches the pelvic floor and continues until the infant is delivered. The length of this stage varies by maternal parity and race/ethnicity (Funai & Norwitz, 2007b). Dystocia is diagnosed in the second stage when the fetal head fails to descend (Frigoletto, 2007).

There are several osteopathic measures that were taken in the second stage of labor. The first of these involves positioning. Positioning is key for good osteopathic management, and is the cornerstone for Dr. Still's technique (Conner, 1928). It is one of the key ways to "drive the wagon through the gate at right angles", as his famous allegory indicates. The birth canal needs to be as short and straight as possible to ease the second stage of labor. The McRobert's position was utilized with our parturients. In this position the parturient hyperflexes her knees and externally rotates her hips. This position has a "positive effect of gravity on the uterus, lessened risk of aortocaval compression and improved acid-base outcomes in the newborns, stronger and more efficient contractions, improved alignment of the fetus for passage through the pelvis, and an increase in pelvic dimensions" (Funai & Norwitz, 2007a, p. 6).

If the fetal head was found to be occiput posterior, then the mother was encouraged to position herself on her hands and knees and allow gravity to pull the baby into the anterior position.

During the delivery of the fetal head the perineum was supported and the passage of the head was slowed, encouraging the woman to stop pushing and "breathe" the baby out. This controlled delivery of the head allowed the soft tissue of the perineum to relax and decrease the risk of a perineal laceration.

The osteopathic physicians delayed clamping of the umbilical cord until the pulsing ceases as much as the Dominican staff physicians would allow. There have been many studies recently, which show a beneficial increase in iron stores without causing harm to the infant. There have been concerns about the neonate receiving too much blood as a result of the delay, but the World Health organization reports that there seem to be self-regulatory mechanisms in place to ensure that the neonate does not receive more of a transfusion than it can handle (WHO, 1998). There were no increased rates of jaundice or

polycythemia in neonates with delayed cord clamping (Funai & Norwitz, 2007a).

Neonates in developing countries, who may not have access to the full spectrum of care seem to especially benefit from delayed cord clamping.

The third stage of labor involves delivery of the placenta. It was delivered in the usual manner. Great care was used to ensure that every standard of care was met with the parturient. If dystocia occurred, despite our osteopathic treatments, then oxytocin, forceps, and offer of cesarean section was applied as needed. The patients in no way suffered harm, and only reaped any potential benefit that OMT had to offer.

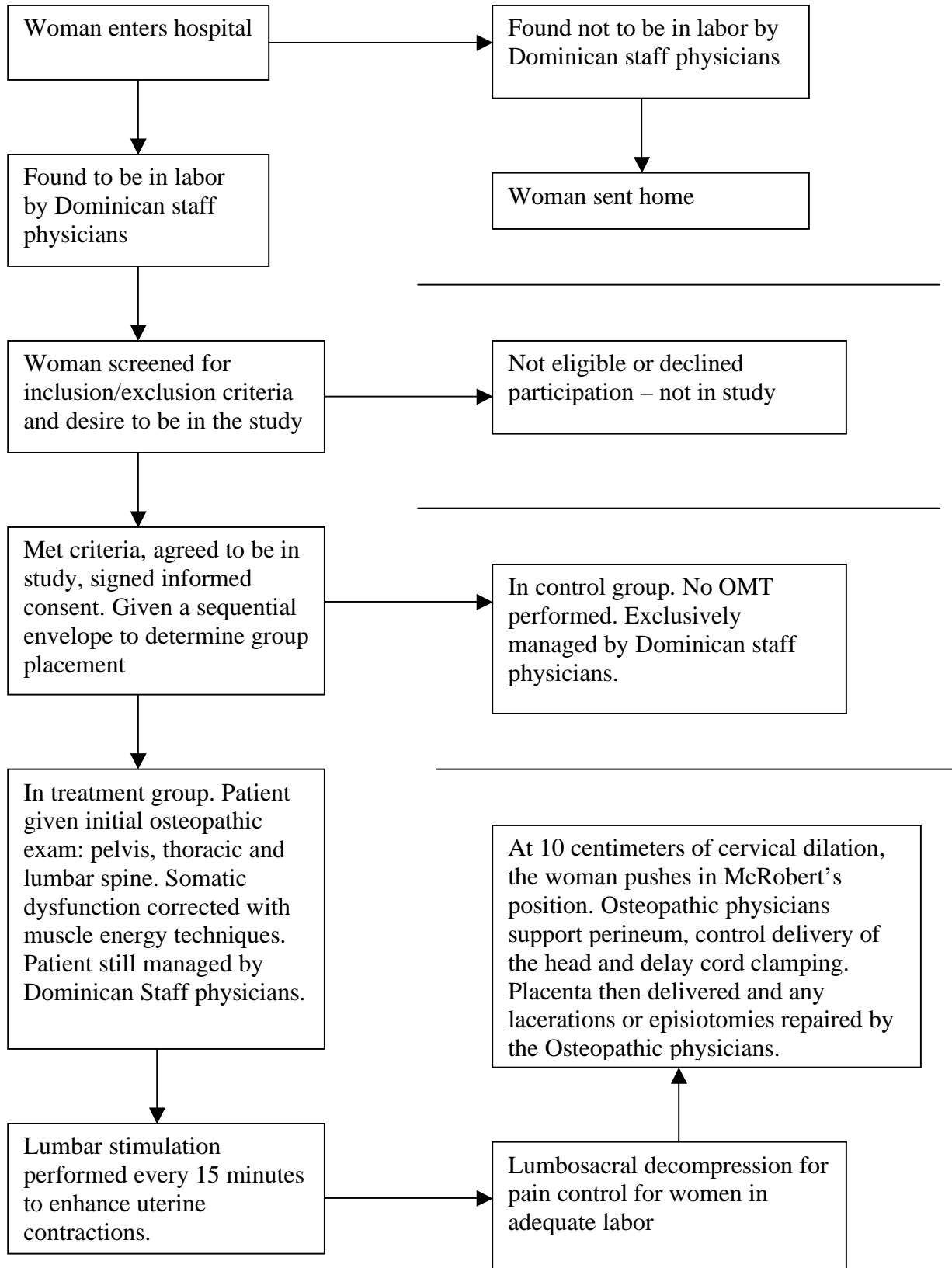


Figure 1. Procedure Flowchart

Chapter 4

*Results**Introduction*

The data were collected at Hospital Maternidad Nuestra Señora de la Altagracia over a six-day period. There was a total of 65 parturients participating in the study. Thirty-three were in the treatment group and thirty-two were in the control group. Those in the treatment group received OMT during labor and delivery as described in the methods section and the Dominican physicians managed those in the experimental group in the usual manner.

Sixty-six parturients were excluded from the study because they met exclusion criteria or declined to participate in the study. Table 1 details the exclusion criteria. The largest exclusion categories were for Pregnancy Induced Hypertension (34.8%), previous cesarean section (27.3%) and those who met the study criteria but declined to participate in the study (16.7%). The study was originally designed to include those with only one cesarean section, but hospital protocol dictated that vaginal births after cesarean are generally avoided.

| Exclusion Criteria | Number of Parturients Excluded | Percentage |
|--|--------------------------------|------------|
| Pregnant with >1 baby | 2 | 3.0% |
| Fetus <34 weeks | 4 | 6.1% |
| Non-vertex presentation | 2 | 3.0% |
| Previous Cesarean | 18 | 27.3% |
| Gestational Diabetes Mellitus | 2 | 3.0% |
| Pregnancy Induced Hypertension | 23 | 34.8% |
| Parturient <15 years old | 1 | 1.5% |
| Parturient >40 years old | 1 | 1.5% |
| Non-viable fetus | 2 | 3.0% |
| Met study criteria but declined to participate | 11 | 16.7% |
| Total excluded | 66 | |

Table 1: Exclusion criteria

The data will be presented using the sequential objectives as a guideline. Statistical significance was set at $\alpha = 0.05$. This was applied to all analyses. All the analyses were performed using SAS version 9.1.3 (Cary, NC, USA). The type of statistical testing will be delineated as each item of data is discussed. Dr. Stephen Werre, Ph.D., a biostatistician at Virginia Tech, performed all of the statistical calculations.

Data Analysis

Baseline Characteristics. The first objective called for a comparison of the baseline characteristics, including age, maternal weight, gravida, parity, centimeters of dilation on admission, and baby's birth weight, between the treatment group and the control groups. Baseline characteristics were recorded for the participants throughout the course of this study. These data are recorded in Table 2. These characteristics were summarized as means with a standard deviation if normally distributed (age, maternal weight, birth weight, and admit centimeters) or medians with a range for variables that appeared skewed (gravida and parity). During univariable analysis, baseline characteristics were compared between the groups (treatment vs control) using a 2 sample ttest if normally distributed, and the Wilcoxon 2 sample test for gravida. Parity and the outcomes were compared between the groups using a fisher's exact test.

The mean age of the parturients in the treatment group was 21.5. The mean age of the parturients in the control group was 23.4 ($P = .095$). The treatment group was 1.9 years younger than the control group. Maternal weight in the treatment group was 149lbs and 153lbs in the control group, for a difference of -3.76 in the treatment group ($P = 0.62$). The median gravity in the treatment group was 1.879 and 2.565 in the control group, for a difference of -0.777 in the treatment group. The median parity in the treatment group was 0.697 and 1.313 in the control group, for a difference of -0.616. The

mean centimeters recorded on admission for the treatment group was 5.4 and 4.9 for the control group, with a difference of 0.5 ($P = 0.24$). The mean birth weight for the babies in the treatment group was 108.5 ounces and 106.5 ounces for the control group, for a difference of +2.02 for the treatment group ($P=0.61$).

| Characteristics | OMT | Control | Difference (OMT-Control) | P value |
|--------------------------------|---------|---------|-----------------------------|---------|
| Age (mean) | 21.545 | 23.406 | -1.8608 | 0.0951 |
| Maternal Weight (mean) | 149.040 | 152.800 | -3.76 | 0.6160 |
| Gravida (median) | 1.879 | 2.656 | -0.777 | |
| Parity (median) | 0.697 | 1.313 | -0.616 | |
| Admit Centimeters (mean) | 5.423 | 4.870 | 0.553 | 0.2416 |
| Baby Weight (oz) (mean) | 108.500 | 106.484 | 2.016 | 0.6147 |

Table 2: Baseline Variables (univariate)

Cesarean Sections, Perineal Lacerations and Episiotomies. The second objective called for a description of the rates of cesarean section, perineal lacerations and episiotomies in Hospital Maternidad Nuestra Señora de la Altagracia in Santo Domingo, Dominican Republic through analysis of the data collected in the control group. The outcomes cesarean section and laceration (categories included none, laceration I & II, and episiotomy) were presented as proportions (also referred to as rates). The control group

had six cesarean sections out of 32 parturients (18.75%). They had 12/26 episiotomies (46.15%) and 4/18 grade I or II perineal lacerations (22.22%). The composite number of women in the control group who had a cesarean section, episiotomy or perineal laceration was 21/32 (65.63%).

| Outcomes | Control |
|--|----------------|
| Cesarean Section (CS) | 6/32 (18.75%) |
| Episiotomy | 12/26 (46.15%) |
| Perineal Laceration (Grade I or II) | 4/18 (22.22%) |
| Composite outcome of CS, Episiotomy, or Perineal Lac | 21/32 (65.63%) |

Table 3: Outcomes for Control

Comparison of Maternal Morbidity Outcome Measures, Cesarean Section, Perineal Lacerations and Episiotomy. The third objective compares selected maternal morbidity outcome measures, cesarean section, perineal laceration and episiotomy, between the treatment group and control group. During multivariable analysis (logistic regression), the association of OMT with the main outcomes was evaluated after adjusting for a selected set of baseline variables (maternal age, maternal weight, parity, and birth weight). For laceration, multinomial logistic regression was chosen over ordinal

logistic regression because the proportional odds assumption was not met. A model that adjusted for only parity is also presented due to the fact stated above.

The cesarean section rate for the treatment group was 3/33 (9.09%) compared to 6/32 (18.75%) in the control group. This gives a P-value of 0.0983. The episiotomy rate for the treatment group was 6/27 (22.22%) compared to 12/26 (46.15%) for the control group. This gives a P-value of 0.0581. The perineal laceration (grade I or II) rate was 5/26 (19.23%) for the treatment group and 4/18 (22.22%) for the control group. This is a P-value of 0.5490. The composite number of women in the treatment group who had a cesarean section, episiotomy or perineal laceration was 14/33 (42.42%) and 21/32 (65.63%).

| Outcomes | OMT | Control | P value |
|--|----------------|----------------|---------|
| Cesarean Section (CS) | 3/33 (9.09%) | 6/32 (18.75%) | 0.0983 |
| Episiotomy | 6/27 (22.22%) | 12/26 (46.15%) | 0.0581 |
| Perineal Laceration (Grade I or II) | 5/26 (19.23%) | 4/18 (22.22%) | 0.5490 |
| Composite outcome of CS, Episiotomy, or Perineal Lac | 14/33 (42.42%) | 21/32 (65.63%) | 0.0235 |

Table 4: Outcomes for entire population of study
Relative Risk adjusted for age, weight, parity, and birth weight

Additionally, the analysis plan was repeated for a subgroup of precipitous parturients (Parity = 0). This subgroup was extracted due to the increased difficulty in delivering these parturients and the unusually large number of them in the treatment group. This group was calculated without controlling for baseline variables. The cesarean rate for the treatment group was 2/21 (9.52%) compared to 3/14 (21.43%) in the control group. This gives a P value of 0.3354. The episiotomy rate for the treatment group was 6/17 (35.29%) compared to 9/12 (75.0%) for the control group. This gives a P value of 0.0419. The perineal laceration rates (grade I and II) were 3/14 (21.43%) for the treatment group compared to 1/4 (25.0%) for the control group. This gives a P value of 0.8797. The composite number of primiparous parturients who received a cesarean section, episiotomy or perineal laceration was 11/21 (52.38%) in the treatment group and 13/14 (92.86%) in the control group. This gives a significant P value of 0.0283.

| Outcomes | OMT | Control | P value |
|---|----------------|----------------|---------|
| Cesarean Section | 2/21 (9.52%) | 3/14 (21.43%) | 0.3354 |
| Episiotomy | 6/17 (35.29%) | 9/12 (75.0%) | 0.0419 |
| Perineal Laceration (Grade I or II) | 3/14 (21.43%) | 1/4 (25.0%) | 0.8797 |
| Composite outcome of CS, Episiotomy or Perineal Lac | 11/21 (52.38%) | 13/14 (92.86%) | 0.0283 |

Table 5: Outcomes for subgroup: Primiparous without controlling for baseline variables

Benefits of OMT in Labor. The fourth objective determines the benefits of OMT in labor through the previous objectives and thus does not include any additional numeric results. This objective will therefore be discussed in detail in Chapter V.

Chapter 5

*Discussion, Summary, Conclusions, and Recommendations**Discussion*

There were numerous unforeseen factors that complicated the research. At Hospital Maternidad Nuestra Señora de la Altagracia, neither forceps or vacuums are used to help extract the baby. This morbidity indicator was therefore removed from the study.

The participants in the study were far fewer than we had anticipated. This is related to several factors. We had to delay starting the study due to cross-cultural factors and the study was terminated early because of a physician strike in the Dominican Republic. Our study was therefore shortened to six days instead of the original ten days for which it was scheduled. The census was low at the hospital during the time of our study and there were a surprisingly large number of parturients who had to be excluded. Just over fifty percent of the women admitted had to be excluded.

The largest exclusion categories were due to previous cesarean section, pregnancy-induced hypertension and the patient's choice to decline participation. There are over twenty criteria that the hospital requires that a woman meet before she undergoes a trial of labor after a previous cesarean delivery. The standard of care for Hospital Maternidad Nuestra Señora de la Altagracia is to avoid vaginal births after having a previous cesarean section. Since it was not possible to offer parturients this option, they were excluded from the study. The original plan was to offer an attempt at a vaginal birth after cesarean delivery if they had only one previous cesarean and it was cut transversely on the uterus. Thus there were 18 (27.3%) women excluded because they had a previous cesarean section. We had to exclude 23 women because they had documented pregnancy-induced hypertension (34.8%). It would be an interesting topic to pursue to determine if a

cause can be found for the increased numbers of pregnancy-induced hypertension in the Dominican Republic. The third major exclusion category was for women who declined to participate in the study. There were 11(16.7%) women who met all other criteria but were hesitant to receive care from foreign medical doctors.

Other factors that complicated this research were the different clinical practices between the osteopathic physicians and the standard of care at Hospital Maternidad Nuestra Señora de la Altagracia. Dominican staff physicians routinely cut episiotomies on their primiparous parturients and were more likely to cut an episiotomy on the multiparous parturients than the osteopathic physicians. Many Dominican physicians found it unacceptable that the osteopathic physicians attempted to avoid the use of episiotomies. They found it necessary to assume care of the treatment patients and cut episiotomies for them. This made the study increasingly difficult, as episiotomy is one of the primary outcome variables. Some of the Dominican physicians permitted delivery without the use of episiotomies, but others refused, as they felt compelled to carry out the standards for the hospital.

It is important to note some of the differences between the treatment and control groups. One of the biggest differences is the number of primiparous parturients in each, as these patients are more difficult to deliver. Out of the thirty-three parturients in the treatment group, twenty-one were primiparous (63.3%). Out of the thirty-two parturients in the control group, only fourteen were primiparous (43.8%). While this does not represent statistically significant differences, it weighed heavily in the research since the Dominican physicians were more aggressive in seeking intervention, namely episiotomy, solely based on primiparity. It is also interesting to note that the average weight in the treatment group was just over two ounces heavier than the control group (108.5oz and 106.5oz respectively).

Summary

The purpose of this study was to explore the effect of Osteopathic Manipulative Treatment (OMT) during labor and delivery on selected maternal morbidity indicators of rate of cesarean section, perineal laceration and episiotomy.

The null hypothesis was that there would be no difference in the rates of cesarean section, perineal tearing or assisted vaginal deliveries between the treatment and control groups. However, the test hypothesis was that Osteopathic Obstetrics would benefit the normalization of vaginal deliveries with a power of 80% at $\alpha = 0.05$.

The hypothesis was tested in a licensed maternity hospital, Hospital Maternidad Nuestra Señora de la Altagracia in the Dominican Republic, with obstetricians licensed by the Dominican Republic who protected patient health for both the control group and the experimental group receiving OMT. Determining the benefits of OMT in labor and delivery is important to advancing research and related literature.

There were 33 parturients in the OMT Treatment group and 32 in the control, for a total of 65 in the trial. The results of a logistic regression analysis using Wald criterion, with a statistical significance set at $\alpha = 0.05$, showed statistical significance in the treatment group for the reduction of rates of episiotomies in the primiparous ($P = .04$) and approaches significance in the combined primiparous and multiparous population ($P = .05$). The percentage of episiotomies in the primiparous treatment group was 35.29% and 75% in the control group. The percentage of episiotomies in the combined primiparous and multiparous groups was 15.15% in the treatment group and 37.5% in the control group. The cesarean rate for the treatment group was 9.09% and 18.75% for the control group ($P = 0.098$). The percentages of grade I & II perineal lacerations were 15.15% for the treatment group and 12.5% for the control group ($P = 0.55$) due to the extensive use of episiotomies in the control group. There were composite calculations made of the total

number of parturients who had a cesarean section, an episiotomy, or a perineal laceration so that overall maternal morbidity in each group could be compared. In the entire population of the study there were fourteen total parturients (42.42%) who had undergone one of the three outcome measures in the treatment group and twenty-one (65.63%) in the control group. This brings an odds ratio of 0.200 and a significant P value of 0.0235.

Though cross-cultural issues made it difficult to perform the research as originally intended, the evidence tends toward Osteopathic Obstetrics providing benefit to parturients. A multi-institutional randomized controlled trial is proposed as the next step for the evaluation of OMT during labor and delivery.

Conclusions

The purpose of this study was to explore the effect of OMT during labor and delivery on selected maternal morbidity indicators of rate of cesarean section, perineal laceration and assisted vaginal delivery. While not statistically significant, there are some trends, despite the cultural barriers and fewer participants than anticipated, that OMT is associated with lower rates of cesarean section, perineal laceration and episiotomy. The power analysis before the study indicated that we needed 347 women to make this study powerful enough to reach significance and thus draw conclusions. Our numbers were much smaller, but show trends and significance in selected areas.

In regard to cesarean sections for the total sample of the study, the treatment group had three and the control group had six. It is important to note that decisions in the management of the laboring patients were not carried out by the researchers but by the Dominican hospital staff. While the researchers did OMT on the treatment group, Dominican physicians made all of the decisions regarding their care. It was always the Dominican physicians who determined if any patient needed to proceed to cesarean section or not. The treatment group had an overall cesarean rate of 9.09% and the control

group rate was 18.75% with an odds ratio of 0.128 (CI = 0.011 – 1.465) and a P value of 0.0983. While this is not statistically significant, given the limited numbers of the study, the numbers favoring OMT provide some evidence that warrants further study. In the primiparous subgroup there was a 9.54% cesarean rate in the treatment group and a 21.43% in the control group with an odds ratio of 0.386 (CI = 0.056 – 2.678) and a P value of 0.3354. Again, the number of reduced cesarean section rate in the treatment group suggests the need for further study on benefits of OMT.

The use of episiotomies was frequently mandated, as discussed above. When allowed, the researchers avoided their use. The researchers voluntarily cut an episiotomy when the baby was not tolerating labor well as evidenced by poor fetal heart tones on auscultation with a stethoscope. In the total sample of the study, there were six episiotomies cut in the treatment group (22.22%) and twelve cut in the control group (46.15%). This failed to reach statistical significance with a P value of 0.058. In the primiparous subgroup there were six episiotomies cut in the treatment group (35.29%) and nine cut in the control group (75.0%). This reached statistical significance with a P value of 0.042. This shows a clear trend in the reduced numbers of episiotomies in the treatment group, despite the frequent intervention by the Dominican physicians. It is also important to note that all of the episiotomies that were cut in the treatment group were cut on primiparous parturients.

The heavy use of episiotomies by the Dominican physicians affects the rates of perineal lacerations that the parturients are likely to undergo. The parturients did not sustain a perineal laceration after having an episiotomy cut, so the parturient who had a cesarean or had an episiotomy were not included in these numbers. In the total sample of the study, there were five out of twenty-six perineal lacerations in the treatment group (19.23%) and four out of eighteen in the control group (22.22%) with an odds ratio of

0.436 and a P value of 0.549. In the primiparous subgroup, there were three out of fourteen perineal lacerations in the treatment group (21.43%) and one out of four in the control group.

There were composite calculations made of the total number of parturients who had a cesarean section, an episiotomy, or a perineal laceration so that overall maternal morbidity in each group could be compared. In the entire population of the study there were fourteen total parturients (42.42%) who had undergone one of the three outcome measures in the treatment group and twenty-one (65.63%) in the control group. This brings an odds ratio of 0.200 and a significant P value of 0.0235. In the primiparous subgroup, the total number of parturients who underwent either a cesarean section, episiotomy or perineal laceration in the treatment group was eleven out of twenty-one (52.38%) and thirteen out of fourteen (92.86%) in the control group. This produces an odds ratio of 0.85 and a significant P value of 0.0283.

This statistically significant finding of decreased overall maternal morbidity gives powerful credence for use of OMT in labor and delivery. Osteopathic Manipulative Treatment is beneficial in labor and delivery for the decrease of maternal morbidity.

This study provides baseline data on the association between OMT and selected maternal morbidity indicators in labor and delivery. It is a landmark pilot study in the field of Osteopathic Obstetrics for future research. Additional research in Osteopathic Obstetrics is needed to provide evidence for Osteopathic Obstetric residency programs to realize the importance of training residents to use OMT in obstetrics.

The study is also ground breaking in the culture and setting of the Dominican Republic. Important findings in differences in standard of care were observed between the U.S. and the Dominican Republic in this hospital. Moreover, there were implications

that these practices are broadly taught and practiced across the Dominican Republic because the doctors in the hospital come from different medical schools.

There were gaps in the knowledge base regarding the normal course of the second stage of labor. The Dominican physicians intervened if the baby did not traverse the birth canal in ten minutes or less for fear of fetal distress if this time was prolonged. The American College of Obstetricians gives one to two hours for the second stage, depending on parity, before the labor is considered abnormal (ACOG, 2000).

Recommendations

Larger, multi-center studies should be completed in America that follows the guidelines established by this study. It would be valuable to examine the effects of OMT in labor and delivery on cesarean section, instrumental delivery, perineal laceration and episiotomy without the cross-cultural issues experienced in this study.

Further study is needed to determine perceived need and rationale for the frequency of episiotomies in the Dominican Republic. An educational program should be designed to address appropriate time in the birth canal, the structural integrity of the perineum and appropriate measures to ascertain fetal well-being while in the birth canal. These were issues that the Dominican physicians presented in their defense of the episiotomy.

To complete international research, a scouting trip should be made before the research begins to establish protocols, agreements and arrangements. There are cross-cultural issues that cannot be discovered via e-mail and phone calls.

Flexibility, patience, and a sense of humor are required to deal with this challenging process in which constant problem solving must be done in order to accomplish the research.

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APPENDIX A**Informed Consent****INFORMED CONSENT**

VIRGINIA COLLEGE OF OSTEOPATHIC MEDICINE**Informed Consent Form for Participants in Research Projects Involving Human Subjects****OSTEOPATHIC MANIPULATIVE TREATMENT DURING LABOR AND DELIVERY****Investigator(s)**

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All investigators will be performing Osteopathic Manipulative Treatments on the parturients in the treatment group in the Dominican Republic.

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I. Investigators' Statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, the possible risks and benefits, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be

in the study or not. This process is called “informed consent.” We will give you a copy of this form for your records.

II. Purpose of this Research/Project

The purpose of this study is to explore the effect that Osteopathic Manipulative Treatment (OMT) during labor and delivery has on the selected problems that the mothers may have. We are specifically looking at cesarean section, if the birth opening tears and if forceps or vacuum have to be used to deliver the baby. Osteopathic doctors are extensively trained, similar to M.D.’s, but have additional training in adjusting muscles and bones for optimal functioning of the body.

If you meet the criteria for the study and desire to be a part of it, then you will be randomly assigned to either the control group, where you would receive the usual care, or the treatment group, where you would receive OMT. We expect to have approximately 600 participants in this study, 300 in the control group and 300 in the treatment group.

III. Procedures

If you are in the control group, you will have the usual care by the staff physicians in the Hospital Maternidad Nuestra Señora de la Altigracia. The osteopathic physicians listed above will care for you if you are in the treatment group. You will be examined by an osteopathic physician. The doctor will listen to your heart, lungs and fetal heart rate. You will have a cervical examination and your back and pelvis will also be checked to see if they are lined up right. If they are not, then it could interfere with normal delivery. The osteopathic physician will do gentle techniques, like massaging your back or gently moving your legs, to bring the back and pelvis back into proper alignment.

The osteopathic physicians will monitor your progress in labor and if you are not progressing as quickly as you should then we will do a “poking” of your lower back to encourage the contractions. We will do this every fifteen minutes. If these treatments do not cause your labor to proceed, then we will rupture your bag of water if it is safe to do so. We will see if this helps labor progress. If you still have not progressed after an hour, then we will start a medicine called oxytocin in an IV. This causes contractions to get stronger. We will not let you be stuck in labor without making progress. You will not be kept waiting for a cesarean section if you need one.

We will encourage you to squat or kneel while you deliver your baby since these positions help make more room in your pelvis. These positions also help your baby be lined up right to come out of your pelvis. We will carefully support your birth opening while the baby is coming out in hopes that you will not tear when you deliver.

We will record your name in the beginning, but we will replace it with numbers when we record the information so that your identity will be protected. Initially be recorded for ease of documentation during labor and delivery. After the data has been collected the random number given to the parturient will replace the names. The data collected will include independent and dependent variables. The independent variables are: parity, age, maternal body mass index, baby’s position during labor and delivery, baby’s birth weight, prenatal care. The dependent variables are: if they received a cesarean section, if the physician had to use forceps to deliver the baby, and the degree of perineal tearing.

No photographs, audio or visual recordings will be made of you or your baby unless you sign the photo release.

IV. Risks, Stress or Discomfort

There are no more than minimal physical risks of having Osteopathic Manipulation during labor and delivery. There may be some stress induced by having to decide whether or not to participate in the study. There may also be some stress associated with being cared for by physicians from another country who are not fluent in Spanish.

Every safeguard has been put into place so that if you are in the osteopathic treatment group that you will meet every standard of care that you would have if you were in the control group. You will not be made to wait unduly for a cesarean section or drug because they are in the treatment group as specified above.

V. Alternatives to Taking Part in this Study

If you choose not to be a part of this study, then the staff physicians at the hospital will deliver you in the usual manner, without the option of being in the osteopathic treatment group.

VI. Benefits of the Study

The benefits of being in the study, which are supported by the literature, are that you will be more likely to have a shorter, less painful labor and less chance of having a cesarean section, tearing of the birth opening and forceps or vacuum delivery. However, no promise or guarantee of benefits has been made to encourage you to participate.

VII. Extent of Anonymity and Confidentiality

Your name and data mentioned above will be collected by either the staff physicians, if you are in the control group, or the osteopathic physicians, if you are in the treatment group. The names will be recorded initially, and then they will be replaced with used randomly assigned number used to indicate your group placement.

Your identity in this study will be treated as confidential. The results of the study may be published but will not give your name or include any identifiable references to you. However, any records or data obtained as a result of your participation in this study may be inspected by the persons conducting this study and/or The Virginia College of Osteopathic Medicine's Institutional Review Board, provided that such inspectors are legally obligated to protect any identifiable information from public disclosure, except where disclosure is otherwise required by law or a court of competent jurisdiction. These records will be kept private in so far as permitted by law.

VIII. Compensation

There is no compensation for participating in this study. The Virginia College of Osteopathic Medicine does not have any monies set aside to provide your care.

If you think you or your baby have an injury related to this study, contact the study staff right away. The study staff will treat you or refer you for treatment by the staff physicians at the hospital.

IX. Freedom to Withdraw

You are free to withdraw from this study at any time without penalty.

You are free to choose whether or not to participate in this study. There will be no penalty if you choose not to participate. In the event you decide to discontinue your participation in the study, please notify Amy Keurentjes, D. O. of your decision so that your participation can be terminated in an orderly fashion.

X. Subject's Responsibilities

“I voluntarily agree to participate in this study. I have the following responsibilities: to participate with the osteopathic physicians during labor and delivery of my child unless I choose to withdraw from the study.”

XI. Subject's Statement

“I have read this consent or have had it read to me. I volunteer to participate in this research study. I have had all of my questions answered. I understand that I will receive a copy of this form. I hereby acknowledge the above and give my voluntary consent. I understand that my consent does not take away any legal rights. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws. I give permission to the researchers to use my medical records as described in this consent form.”

| | | |
|-----------------------------|--|------|
| Printed name of participant | <hr style="width: 80%; margin: 0 auto;"/> Signature of participant | Date |
|-----------------------------|--|------|

When participant in a minor:

| | | |
|------------------------|---|------|
| Printed name of parent | <hr style="width: 80%; margin: 0 auto;"/> Signature of parent | Date |
|------------------------|---|------|

When subject is not able to provide consent:

| | | |
|--------------------------------|--------------------------------------|------|
| Printed name of representative | _____ Signature of representative | Date |
|--------------------------------|--------------------------------------|------|

Relationship of representative to participant

Should I have any pertinent questions about this research or its conduct, research subjects' rights, and whom to contact in the event of a research-related injury to the subject, I may contact:

Amy Keurentjes, D.O., Ph.D. candidate
 Phone: 540-818-8264
ashanks@vcom.vt.edu

Anita Showalter, D.O.
anitash@yvfwc.org

Charlene James, D.O., Ph.D.
jcglover@pol.net

Aaron Vawter, D.O.
vawterski@hotmail.com

Brianna Cross, pre-doctoral OMM fellow
briannacross@gmail.com

Diane Sabado, M.D.
drdiane@corazondelsiervo.org

For questions I may have about this study.

VCOM IRB Chairman
 Hara P. Misra, D.V.M., Ph.D.
 (540) 231-3693, misra@vt.edu

For questions I may have about my rights as a research subject.

This Informed Consent is valid from 2/1/08 *to* 3/1/08 .

VIRGINIA COLLEGE OF OSTEOPATHIC MEDICINE**La Forma informada del Consentimiento para Participantes en Proyectos de Investigación que Implican los Sujetos del Humano****EL TRATAMIENTO OSTEOPATICO del MANIPULATIVO DURANTE PARTIDO LABORISTA Y la ENTREGA****El investigador (investigadores)**

Amy Keurentjes, D.O., Ph.D. candidate

Phone: 540-818-8264

ashanks@vcom.vt.edu

Anita Showalter, D.O.

anitash@yfwc.org

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briannacross@gmail.com

Diane Sabado, M.D.

drdiane@corazondelsiervo.org

Todos los investigadores realizarán los tratamientos manipulantes de Osteopathic en los parturientes en el grupo del tratamiento en la República Dominicana.

Teléfono del número de teléfono de emergencia 24-Hour

Amy Keurentjes, D.O del candidato de Ph.D.:

540-818-8264

I. La declaración de los investigadores

Estamos pidiendo que usted estuviera en un estudio de la investigación. El propósito de esta forma del consentimiento es darle la información que usted necesitará ayudarle a decidir si ser en el estudio o no. Lea por favor la forma cuidadosamente. Usted puede hacer preguntas acerca del propósito de la investigación, los riesgos y las ventajas posibles, y cualquier cosa sobre la investigación o esta forma que no esté clara. Cuando hemos contestado a todas sus preguntas, usted puede decidir si usted desea ser en el estudio o no. Este proceso se llama "consentimiento informado." Le daremos una copia de esta forma para sus expedientes.

II. El propósito de este Research/Project

El propósito de este estudio es explorar el efecto que el tratamiento manipulante de Osteopathic (OMT) durante trabajo y entrega tiene en los problemas seleccionados que las madres pueden tener. Estamos mirando específicamente la sección cesariana, si la abertura del nacimiento se rasga y si los fórceps o el vacío tienen que ser utilizados para

entregar al bebé. Entrenan, similar a M.D.'s, pero tienen a los doctores de Osteopathic extensivamente entrenamiento adicional en el ajuste de los músculos y de los huesos según el funcionamiento óptimo del cuerpo. Si usted resuelve los criterios para el estudio y desea ser una parte de ella, después le asignarán aleatoriamente a cualquier el grupo de control, donde usted recibiría el cuidado generalmente, o el grupo del tratamiento, donde usted recibiría OMT. Esperamos tener aproximadamente 600 participantes en este estudio, 300 en el grupo de control y 300 en el grupo del tratamiento.

III. Los procedimientos

Si usted está en el grupo de control, usted tendrá el cuidado generalmente de los médicos del personal en el general Hospital Maternidad Nuestra Señora de la Altigracia. Los médicos osteopathic enumeraron arriba cuidarán para usted si usted está en el grupo del tratamiento. A un médico osteopathic le examinará. El doctor escuchará su corazón, pulmones y ritmo cardíaco fetal. Usted tendrá una examinación cervical y su parte posteriora y pelvis también serán comprobadas para considerar si se alinean a la derecha. Si no son, después podría interferir con entrega normal. El médico osteopathic hará técnicas apacibles, como el masaje de su parte posteriora o suavemente la mudanza de sus piernas, para traer la parte posteriora y la pelvis nuevamente dentro de la alineación apropiada. Los médicos osteopathic supervisarán su progreso en trabajo y si usted no está progresando tan rápidamente como usted debe entonces haremos un "empuje" de su más bajo de nuevo a animamos las contracciones. Haremos esto cada quince minutos. Si estos tratamientos no hacen su trabajo proceder, después romperemos su bolso del agua si es seguro hacer tan. Veremos si esto ayuda a progreso de trabajo. Si usted todavía no ha progresado después de una hora, entonces comenzaremos una medicina llamada oxytocin en un intravenoso. Esto hace contracciones conseguir más fuertes. No le dejaremos ser pegado en trabajo sin la fabricación de progreso. Le no guardarán el esperar de una sección cesariana si usted necesita uno. Le animaremos a que se ponga en cuclillas o se arrodille mientras que usted entrega a su bebé puesto que estas posiciones ayudan a hacer más sitio en su pelvis. Estas posiciones también ayudan a su bebé a ser alineadas a la derecha para salir de su pelvis. Apoyaremos cuidadosamente su abertura del nacimiento mientras que el bebé está viniendo hacia fuera en esperanzas que usted no se rasgará cuando usted entrega. Registraremos su nombre en el principio, pero lo substituiremos por números cuando registramos la información de modo que su identidad sea protegida inicialmente se registre para la facilidad de la documentación durante trabajo y entrega. Después de que se hayan recogido los datos el número al azar dado al parturient substituirá los nombres. Los datos recogidos incluirán variables independientes y dependientes. Las variables independientes son: paridad, edad, índice maternal de la masa del cuerpo, posición del bebé durante trabajo y entrega, peso del nacimiento del bebé, cuidado prenatal. Las variables dependientes son: si recibieron una sección cesariana, si el médico tuvo que utilizar el fórceps para entregar al bebé, y el grado de rasgado perineal. No se hará ningunas grabaciones de las fotografías, audio o visuales de usted o de su bebé a menos que usted firme el relsease de la foto.

IV. Los riesgos, la tensión o el malestar

Allí son no más que riesgos físicos mínimos del tener manipulación de Osteopathic durante trabajo y entrega. Puede haber una cierta tensión inducida por tener que decidir a si o no participar en el estudio. Puede también haber una cierta tensión asociada a ser cuidado para por los médicos de otro país que no son fluidos en español. Cada salvaguardia se ha puesto en lugar de modo que si usted es en el grupo osteopathic del

tratamiento que usted resolverá cada estándar del cuidado que usted tendría si usted estaba en el grupo de control. Le no harán para esperar indebidamente una sección cesariana o una droga porque están en el grupo del tratamiento según lo especificado arriba.

V. Los alternativas a participar en este estudio

Si usted elige no ser una parte de este estudio, entonces los médicos del personal en el hospital le entregarán de la manera generalmente, sin la opción de estar en el grupo osteopathic del tratamiento.

VI. Las ventajas del estudio

Las ventajas de estar en el estudio, que son apoyadas por la literatura, son que usted será más probable tener un trabajo más corto, menos doloroso y menos ocasión del tener una sección cesariana, el rasgado de la abertura del nacimiento y el fórceps o entrega del vacío. Sin embargo, no se ha hecho ninguna promesa o garantía de ventajas para animarle a que participe.

VII. El grado del anonimato y del secreto

Su nombre y datos mencionados arriba será recogido por cualquier los médicos del personal, si usted está en el grupo de control, o los médicos osteopathic, si usted está en el grupo del tratamiento. Los nombres serán registrados inicialmente, después serán substituidos por aleatoriamente usado el assigned number usado para indicar su colocación del grupo. Su identidad en este estudio será tratada como confidencial. Los resultados del estudio se pueden publicar pero no darán su nombre ni incluirán cualquier referencia identificable a usted. Sin embargo, cualesquiera expedientes o dato obtenidos como resultado de su participación en este estudio se pueden examinar por las personas que conducen este estudio y/o la universidad de Virginia del comité examinador institucional de la medicina de Osteopathic, a condición de que obligan a tales inspectores legalmente proteger cualquier información identificable contra el acceso público, excepto donde el acceso es requerido de otra manera por la ley o una corte de la jurisdicción competente. Estos expedientes serán mantenidos privados adentro en cuanto son permitidos por la ley.

VIII. La remuneración

Allí no es ninguna remuneración para participar en este estudio. La universidad de Virginia de la medicina de Osteopathic no tiene ninguna dineros puesta a un lado para proporcionar su cuidado. Si usted piensa que usted o su bebé tiene lesión relacionada con este estudio, entre en contacto con a personal del estudio enseguida. El personal del estudio le tratará o le referirá para el tratamiento de los médicos del personal en el hospital.

IX. La libertad para retirarle

Está libre retirarse de este estudio en cualquier momento sin pena. Usted está libre elegir si o no participar en este estudio. No habrá pena si usted elige no participar. En el acontecimiento usted decide continuar su participación en el estudio, notifica por favor a amy Keurentjes, D. O. de su decisión para poder terminar su participación en una manera ordenada.

X. Responsabilidades Sujetas

"Que acuerdo voluntariamente participar en este estudio. Tengo las responsabilidades siguientes: para participar con los médicos osteopathic durante trabajo y entrega de mi niño a menos que elija retirarme del estudio."

XI Declaración Sujeta

"He leído este consentimiento o lo he tenido leído a mí. Me ofrezco voluntariamente a participar en este estudio de la investigación. He tenido todas mis preguntas contestadas. Entiendo que recibiré una copia de esta forma. Reconozco por este medio el antedicho y doy mi consentimiento voluntario. Entiendo que mi consentimiento no quita el ninguna derechas legal. Entiendo más lejos que no se piensa nada en esta forma del consentimiento para substituir ningún federal aplicable, estado, o los leyes locales. Doy el permiso a los investigadores de utilizar mis expedientes médicos según lo descrito en esta forma del consentimiento."

el _____ del _____ imprimió
el nombre de la firma del participante de la fecha del participante Cuando participante en un menor de edad:

el _____ del _____ imprimió
el nombre de la firma del padre de la fecha del padre Cuando el tema no puede proporcionar consentimiento:

el _____ del _____ imprimió
nombre de la firma representativa de la fecha representativa

Relación del representante al participante Si tengo cualquier pregunta pertinente sobre esta investigación o su conducta, la investigación sujetó las derechas, y quién a entrar en contacto con en el acontecimiento de lesión investigacio'n-relacionada al tema, puedo entrar en contacto con:

Amy Keurentjes, D.O., Ph.D. candidate
Phone: 540-818-8264
ashanks@vcom.vt.edu

Anita Showalter, D.O.
anitash@yfwc.org

Charlene James, D.O., Ph.D.
jcglover@pol.net

Aaron Vawter, D.O.
vawterski@hotmail.com

Brianna Cross, pre-doctoral OMM fellow
briannacross@gmail.com

Diane Sabado, M.D.
drdiane@corazondelsiervo.org

Para las preguntas puedo tener sobre este estudio.

Presidente Hara P. Misra, D.V.M., Ph.D de VCOM IRB. (540) 231-3693, misra@vt.edu
para las preguntas que puedo tener sobre las mis derechas como tema de la investigación.

Este consentimiento informado es válido de ____ del ____ 2/1/08 al ____ 3/1/08 ____.

APPENDIX B

Muscle Energy Techniques

All muscle energy techniques have been quoted directly from Dr. DiGiovanna and Dr. Schiowitz's book, *An Osteopathic Approach to Diagnosis and Treatment*.

Thoracic Spine

- Type I Group Curve:
 1. Patient Position: seated, feet on the floor, weight equally distributed on the buttocks
 2. Physician Position: standing behind the patient and slightly to the side of the convexity.
 3. Technique:
 - a. The physician monitors at the apex of the curve being treated.
 - b. The physician induces side-bending toward the convexity and rotation away from the convexity by applying a caudal and anterior force to the ipsilateral shoulder. Motion is induced down to the monitoring finger at the apex of the curve.
 - c. If the patient becomes unbalanced by the above movement a translatory force should be applied toward the concavity. Note that the spine is kept in neutral position (i.e., no flexion or extension).
 - d. The patient then side-bends toward the concavity (the freedom of motion) while the physician maintains a resistance on the shoulder closest to him (i.e., the side of the convexity).
 - e. The force is held for 2 or 3 seconds; then the patient relaxes.

- f. After 2 seconds of rest, the new motion barriers to side-bending and rotation are engaged.
 - g. The procedure is repeated twice more.

- Type II Single-Segment Somatic Dysfunction (Upper Thoracic Region: T1-4)
 - 1. Patient Position: seated, with feet on the floor.
 - 2. Physician Position: standing behind the patient and to the side of the motion barriers.
 - 3. Technique:
 - a. One hand monitors the involved vertebra to detect motion.
 - b. The other hand holds the patient's head, or the arm is wrapped around it turban-style to control its motion and to provide a resistance to the patient's motion.
 - c. The patient's neck is either flexed or extended to its motion barrier, while the physician monitors at the vertebra being treated. The patient's head is then side-bent and rotated into the barriers to motion.
 - d. The patient is instructed to side-bend or rotate his head toward the freedom of motion against the physician's resistive force.
 - e. This is held 3 to 4 seconds; then the patient relaxes.
 - f. New motion barriers are engaged.
 - g. The process is repeated twice more.
 - h. A passive stretch is given.

- Type II Single-Segment Somatic Dysfunction (Middle and Lower Thoracic Region)

1. Patient Position: seated, with the feet on the floor
2. Physician Position: standing behind the patient and to the side of the motion barriers.
3. Technique:
 - a. The physician places one arm over the patient's shoulder on the side of the motion barriers. He may use either his axilla or his forearm.
 - b. The patient is flexed or extended to the motion barrier. Extension may be achieved by asking the patient to sit up straight or to stick his belly out. Flexion is achieved by having the patient slump forward. Motion should be to the involved segment.
 - c. Using his axilla or arm, the physician side-bends the patient and rotates him into the motion barriers at the involved segment.
 - d. If the dysfunction is low enough that side-bending unbalances the patient, a translatory force in the opposite direction will aid in keeping both buttocks on the table.
 - e. The patient then side-bends or rotates toward the freedom of motion. The physician provides a resistance with his arm. This is held for 3 to 4 seconds.
 - f. The patient relaxes, and the new motion barriers are engaged.
 - g. The process is repeated twice more.
 - h. A passive stretch is given.

Lumbar Spine

- Type I Neutral (Group) Curves

- a. Patient Position: lateral recumbent with concavity toward the table; therefore, the posterior rotated transverse processes are up.
 - b. Physician position: standing at the side of the table facing the patient.
 - c. Technique:
 - a. The physician monitors the apex of the curve with one hand.
 - b. The physician flexes the patient's hips to 90 degrees.
 - c. The physician side-bends the lumbar spine to the apex by elevating the patient's ankles with the nonmonitoring hand.
 - d. The patient is then instructed to push his feet toward the floor for 3 seconds.
 - e. The physician provides resistance, producing a static contraction.
 - f. The patient is asked to relax.
 - g. The physician further elevates the patient's legs until motion is felt at the new barrier.
 - h. The procedure is repeated three times.
 - i. A passive stretch is added.
- Type II (Single-Segment) Dysfunction – FLEXED
 1. Patient Position: lying on the table in a lateral recumbent position. The posteriorly rotated transverse process to be treated faces down, toward the table.
 2. Physician position: standing at the side of the table facing the patient.
 3. Technique:

- a. The physician instructs the patient to lie on his side with the posterior transverse process down.
- b. The physician stands facing the patient and monitors the somatic dysfunction with one hand at the interspinous region.
- c. With the other hand the physician flexes the patient's hips and knees until motion is felt at the level below the dysfunction.
- d. The patient straightens his lower leg and the physician extends it until motion is felt at the same level. The flexed upper leg is "locked" in place with the dorsum of the foot of the top leg placed in the popliteal space of the lower leg by the physician.
- e. The physician changes hands so that the caudal (with respect to the patient) hand is now monitoring the involved segment.
- f. With his other hand the physician grasps the patient's lower arm and pulls it upward, causing rotation of the torso, until motion is felt at the level of the restriction.
- g. Further rotation and localization are achieved by directing the patient to use the top hand to grasp the table edge behind his back.
- h. The physician places his cephalic hand on the patient's shoulder.
- i. The patient is instructed to take a deep breath, then exhale. Thereafter the patient is directed to reach farther down the table edge. The physician places light pressure against the patient's shoulder and more precisely localizes the somatic dysfunction.
- j. The physician again switches hands and uses his cephalic hand to monitor the level of the restriction.

- k. The physician grasps the ankle of the patient's upper leg and elevates it until the lumbar spine side-bends to the motion barrier.
 - l. The patient pushes his elevated foot down toward the table while the physician maintains resistance, producing a static contraction.
 - m. After 3 seconds, the patient is asked to relax.]The physician then increases extension, side-bending, and rotation into the new motion barriers by again elevating the patient's upper ankle.
 - n. The procedure is repeated three times.
 - o. A passive stretch is given.
- Type II (Single-Segment) Dysfunction – EXTENDED
 1. Patient Position: lying on the table in a lateral recumbent position. The posteriorly rotated transverse process to be treated faces up. The patient is then placed in the modified Sims position.
 2. Physician Position: standing at the side of the table facing the patient.
 3. Technique:
 - a. The patient is instructed to lie on his side with the posterior transverse process up.
 - b. The physician faces the patient and monitors the somatic dysfunction with his cephalic hand.
 - c. The physician flexes the patient's knees and hips until motion is felt at the area of somatic dysfunction.

- d. The physician switches monitoring hands so that the caudal (with respect to the patient) hand is on the somatic dysfunction.
- e. Rotation is achieved by placing the patient in the lateral Sims position.
- f. Additional rotation is induced by having the patient inhale, then exhale and simultaneously reach toward the floor.
- g. The physician pushes down on the shoulder with his cephalic hand until the torso is rotated down to the monitored segment, exaggerating the Sims position.
- h. The patient's legs are lowered off the side of the table to create lumbar side-bending up to the restricted area.
- i. Since this position is uncomfortable for the patient, the physician may either lace a pillow under the patient's lower knee or sit behind the patient and put his thigh between the patient's legs and the table (this position requires the physician to change the hand monitoring).
- j. The patient pushes his feet toward the ceiling while the physician resists, creating an isometric contraction, which is held for 3 seconds.
- k. The patient relaxes. The physician engages a new motion barrier by further lowering the patient's legs.
- l. The procedure is repeated three times.
- m. A passive stretch is given.

APPENDIX C

Forms for Data Collection

CRITERIOS DE ELIGIBILIDAD Y EXCLUSIÓN
ELIGIBILITY AND EXCLUSIONARY CRITERIA



| INCLUSIÓN Inclusion | SÍ | NO |
|--|--------------------------|--------------------------|
| <u>Estoy embarazada</u> con un <u>solo</u> bebé_ I am only pregnant with one baby | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>Tengo</u> por lo menos 34 semanas de embarazo I am at least 34 weeks pregnant | <input type="checkbox"/> | <input type="checkbox"/> |
| La cabeza del bebé <u>está hacia</u> abajo _____ The baby's head is pointed down | <input type="checkbox"/> | <input type="checkbox"/> |
| He tenido 0 o 1 <u>cesáreo</u> con un corte transversal (a través del útero) I have had 0 or 1 cesarean with a transverse cut (across the uterus) | <input type="checkbox"/> | <input type="checkbox"/> |

| EXCLUSIÓN Exclusion | | |
|---|--------------------------|--------------------------|
| He tenido 2 o más <u>cesáreos</u> con cortes transversales (a través del útero) I have had 2 or more cesareans with a transverse cut (across the uterus) | <input type="checkbox"/> | <input type="checkbox"/> |
| He tenido 1 o más <u>cesáreos</u> con corte vertical (arriba y abajo del útero) I have had 1 or more cesareans with a vertical cut (up and down the uterus) | <input type="checkbox"/> | <input type="checkbox"/> |
| He tenido diabetes gestacional con este embarazo (altos niveles de azúcar de l sangre) I have had gestational diabetes with this pregnancy (high blood sugar levels) | <input type="checkbox"/> | <input type="checkbox"/> |
| He tenido hipertensión gestacional con este embarazo (<u>alta presión</u> arterial) I have had gestational hypertension with this pregnancy (high blood pressure) | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>Tengo menos de</u> 15 años de <u>edad</u> I am younger than 15 years old | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>Tengo</u> más de 40 años de <u>edad</u> _____ I am older than 40 years old | <input type="checkbox"/> | <input type="checkbox"/> |

¿Calificado para la investigación?
Qualified for research?

SÍ

NO

Si sí, entonces incorpore el número de identificación en el brazal al sobre:
If yes, then enter Identification Number on the armband in the envelope:

Identification Number: _____

Last Name: _____

First Name: _____

Age: _____ Weight: _____ Height: _____ Gravida/Parity: _____
PNC: Yes or No

FIRST STAGE:

Fetal Presentation: _____

Patient Received an Amniotomy: Yes or No

Patient Received an Epidural: Yes or No

Patient was Started on Pitocin: Yes or No

Cesarean Section Performed: Yes or No If yes, why?

SECOND STAGE:

Maternal Position: _____

Forceps or vacuum used: Yes or No

Episiotomy performed: Yes or No

Perineum Lacerated: Yes or No If yes then: I II III IV

Cesarean Section performed: Yes or No If yes, why?

OMT:

Lesion Identified: Thoracic Lumbar Pelvis

Patient Received Muscle Energy: Thoracic Lumbar Pelvis

Patient Received Lumbar Stimulation at: 0 min 15 min 30 min 45min

Other:

BABY:

Birth Weight:

Complications:



Número de Identificación:
(Identification Number) _____

Apellido: _____ Primer Nombre:
(Last Name) _____ (First Name) _____

Edad: _____ Peso: _____ Altura: Gravida/Paridad: _____
(Age) (Weight) (Height) (Gravida/Parity)
Atención Prenatal: (PNC) Sí o No

PRIMERA ETAPA:
(First Stage)

Presentación Fetal _____
(Fetal Presentation)

El paciente recibió un amniotomía: Sí o No
(Patient Received an Amniotomy)

El paciente recibió un epidural : Sí o No
(Patient Received an Epidural)

Administraron pitocin al paciente: Sí o No
(Patient was Started on Pitocin)

Cesáreo realizado: _____ Sí o No ¿En caso que sí, por qué?
(Cesarean Section Performed)

SEGUNDA ETAPA
(Second Stage)

Posición maternal _____
(Maternal Position)

Fórceps o vacío usado: Sí o No
(Forceps or vacuum used)

Episiotomía realizada: Sí o No
(Episiotomy performed)

Laceró el perinéo : Sí o No En caso que sí: I II III IV
(Perineum Lacerated)

Cesáreo realizado: _____ Sí o No ¿En caso que sí, por qué?
(Cesarean Section performed)

BEBÉ:
(Baby)

Peso del Nacimiento
(Birth Weight)

Complicaciones
(Complications)