Title: Rapidly Absorbing Polyglactin 910 Versus Monocryl for Laceration Repair)

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NCT #: NCT03184077

Unique Protocol ID: HM20000992

Document approval date: July 21, 2014

Document Type: Protocol and SAP

Rapidly absorbing polyglactin 910 versus monocryl for laceration repair: a randomized controlled trial

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Study site: Virginia Commonwealth University Medical Center Labor and Delivery

Research Synopsis

Study title - Rapidly absorbing polyglactin 910 versus monocryl for laceration repair: a randomized trial
Study Population – recently postpartum women who delivered at Virginia Commonwealth University Labor and Delivery with a first or second degree laceration or episiotomy requiring repair
Study Design – Prospective, randomized
Sample Size – 400
Study Duration – 24 months
Primary Objective – dyspareunia
Secondary Objectives – perineal pain

Background and Significance

Obstetric perineal trauma is a worldwide problem impacting approximately 85% of women having vaginal deliveries with at least two-thirds requiring perineal repair. The associated pain and discomfort can have a great impact on a woman in the immediate post partum time period while she adjusts to the demands of caring for a newborn. Not uncommonly this pain can persist for several months and 20% may experience long-term problems with persistent pain and dyspareunia. It is important to minimize the negative effects of perineal lacerations by choosing the correct suture material and using the proper technique to reapproximate the anatomy.

Sutures are used to close the wound, minimize bleeding, prevent infection and promote healing. Various sutures have been used to reapproximate perineal lacerations. The ideal suture choice would have minimal tissue reactivity and be absorbed once the wound has healed to prevent tissue scarring and inflammatory reaction. Suture that remains in place longer than needed may impair healing leading to wound infection and breakdown or scarring with subsequent pain. A variety of suture materials have been used to close perineal lacerations, including catgut, absorbable braided and monofilament materials, and newer rapidly absorbed braided material.

Catgut suture is made from collagen derived from the intestines of sheep and cows and is reported to cause an increased inflammatory response in the tissues due to the fact that it is broken down by proteolytic enzymes and phagocytosis (Irvin 1981). Chromic catgut suture is treated with chromate salts to slow down the absorption process and decrease the inflammatory response. A Cochrane review of 18 RCTs compared absorbable synthetic suture to chromic catgut for perineal repair and found that absorbable synthetic material significantly reduced short-term perineal pain, analgesia use within 10 days, rates of suture dehiscence and resuturing compared with catgut. However, there were no clear differences in long-term pain and dyspareunia.

Common synthetic absorbable sutures used in laceration repair include polyglycolic acid, polyglactic 910, and monofilament poliglecaprone 25. Both polyglycolic acid and polyglactin 910 are braided sutures. Polyglycolic acid is designed to be absorbed by the body in 120 days and polyglactin 910 is usually absorbed by 90 days. Both sutures are similarly designed to reduce bacterial adherence and

tissue drag. Monofilament suture is also designed to have reduced tissue drag and minimal tissue reaction. It is absorbed from the body in 90 to 110 days.

A more recent type of polyglactin 910 in now being commonly used in perineal laceration repair. This more rapidly absorbable material is identical to standard polyglactin 910 in chemical composition but due to change in the manufacturing process, is absorbed in less time. This suture is completely absorbed by the tissue in 42 days compared to 90 days with standard polyglactin 910. This more rapid absorption is presumed to promote wound healing with less scarring and inflammatory response.

The 2010 Cochrane systematic review of absorbable suture material for perineal repair included comparisons of standard sutures with rapidly absorbing synthetic (five trials) and monofilament sutures (one trial). In the comparison of standard synthetic with rapidly absorbing sutures, short- and long-term pain were similar. One trial found those with rapidly absorbing sutures required less analgesics at 10 days. More women with standard synthetic suture required suture removal compared to the rapidly absorbed group. There was no evidence of significant difference between groups for long-term pain or dyspareunia. The one trial comparing monofilament with standard polyglycolic suture found no difference for most outcomes. There have been no studies to date comparing rapidly absorbable suture to monofilament.

The purpose of this study is to compare monofilament suture with the rapidly absorbing polyglactin 910. We will compare pain, rate of dyspareunia, and overall sexual function.

Objectives:

Primary Objective

To evaluate the rates of dyspareunia using a female sexual function index -6 survery with rapidly absorbing polyglactin 910 compared to monocryl.

Secondary Objectives

To assess overall perineal pain using a pain scale.
To assess overall sexual function.

Study design/methodology:

This randomized controlled trial will be conducted and VCU medical center comparing 2 types of suture: rapid polyglactin 910 (Vicryl Rapide) and monofilament (Monocryl) for first and second-degree lacerations or uncomplicated episiotomies requiring suture repair. Patients will be enrolled in the study immediately after vaginal delivery if a laceration occurs spontaneously or if episiotomy if performed. Patients will be randomized to one of the 2 sutures after enrollment. Inclusion criteria include English speaking, patients with first and second degree spontaneous lacerations or those with midline or mediolateral epsiotomies that were uncomplicated, and hemodynamically stable paitents. Exclusion criteria include non-english or Spanish speaking, women without laceration or with third or fourth degree lacerations.

Randomization will be obtained via computer generation in consecutively numbered, opaque sealed envelopes with the name of one of the suture materials. The envelope will be opened at the time of repair of perineal laceration once inclusion criteria have been met by the physician or midwife performing the laceration repair. Repair with the chosen suture will be performed using the continuous suture technique using a 3-0 suture. Various maternal and fetal characteristics will be recorded

including maternal age, gravity and parity, gestational age at delivery, birth weight, insurance type and race.

In the immediate postpartum time period while the patient is hospitalized, patients will be given ibuprofen 600 mg every 6 hours or oxycodone 5mg and acetaminophen 325mg every 4 hours as needed for pain. If sufficient pain control is not achieved with these medications, then morphine 4mg IV will be administered until appropriate pain control is satisfactory. They will also be give the standard prescriptions that are routinely dispensed to all postpartum patients including ibuprofen 600mg every 6 hours and oxycodone 5mg and acetaminophen 325mg every 4 hours to be used as needed.

Pain will be evaluated using a pain scale at 6 week telephone interview. At three months postpartum another telephone interview will be conducted and six questions of the Female Sexual Function Index will be asked.

Study Population:

Inclusion criteria include English speaking patients with first and second degree spontaneous lacerations or those with midline or mediolateral episiotomies that were uncomplicated, and hemodynamically stable patients.

Exclusion criteria include non-english speaking women without laceration or with third or fourth degree lacerations.

Study Duration/ Study Timeline:

Stage 1 – Enrolling patients and randomization
Stage 2 – follow up at 6 weeks and 3 months
Stage 3 – data analysis
Stage 4 – presentation and publication

Projected start date: 8/2014
Total length of time: 36 months
Approximate end date: 8/2017

Statistical Analysis Plan:

A chi square analysis and Fisher's exact test will be used for data analysis.
A goal sample size of 400 patients will be included in the study. With 200 patients in each arm of the study and assuming a standard deviation of 1, with a 15% loss to follow up, we would be able to detect a difference in pain scores of 0.25 or more.

Patients will be excluded from analysis if they are lost to follow up after the repair. Attempts will be made to contact the patient via telephone. If the patient is lost to follow up after their 6 week visit, this data will be included in the analysis.

Informed Consent Process:

Informed consent will be obtained after delivery, prior to laceration repair.

Privacy and confidentiality:

Subject's names will be kept on a password protected database and will be linked only with a study identification number for this research. There are no patient identifiers. All data will be entered into a computer that is password protected.

Risk/Benefit:
Risk to participants: This study does not present any risks to the participants.
Benefits to Participants: This study does not present any direct benefit to the participants. However the study does provider an opportunity to gain a better understanding of suture maternal that can potentially minimize pain and dyspareunia that will benefit women undergoing vaginal delivery and laceration repair in years to come.

Data Safety Monitoring:
A mid-point statistical analysis will be performed to ensure patient safety

Conflict of Interest:
The principal and co-investigators have no conflicts of interest to report.

References:

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