

RANDOMIZED CLINICAL TRIAL OF DIATHERMY VERSUS SCALPEL IN ABDOMINAL WALL INCISION DURING REPEAT CESAREAN DELIVERY

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INTRODUCTION / BACKGROUND

Cesarean delivery (CD) is the operative mode of the delivery, which includes laparotomy (skin incision) and hysterotomy (uterine incision) in order to facilitate the delivery of the newborn. In the modern obstetric practice in the United States one in three women who gave birth did so by CD. (1). Cesarean birth can be life-saving for the fetus, the mother, or both in certain cases. The rate of primary CD has increased and more women prefer elective repeat cesarean delivery (ERCD) (2). This increased rate of cesarean deliveries is associated with the short- and long-term maternal complications (3) such as RBC transfusion (2). Among approaches used to reduce the rate of the postoperative complications are prophylactic administration of antibiotics (4) and improvement of surgical techniques (5). In particular, the improvement of surgical technique could contribute to more than two-fold decrease in post-operative morbidity (5). The application of techniques of the abdominal incision during CD is associated with hysterotomy approaches and subsequently maternal morbidity in specific patient populations (6).

During surgical procedures, one of the widely used approaches to decrease blood loss, surgery time and thus post-operative complications is tissue dissection by electrosurgery, which is defined as the process of applying high-frequency electric current to the tissues to cut, coagulate, and desiccate (7). After the introduction of electrosurgery into the practice of surgery in 1926 by William T Bovie and Dr. Harvey W Cushing (8), it has since become a powerful tool in different surgical subspecialties (9)(7).



Electrosurgical instruments are widely used for tissue dissections and to control bleeding, as an easy and safe surgical approach, but their use in making skin incisions is limited. The major purported disadvantages of electrosurgical skin incisions are fears of deep burns; with resultant scarring (10), slower wound healing, and increased postoperative pain. However, recent meta-analyses showed decreased incision time, blood loss and post-operative pain with no significant difference in wound infection rates or scar (13)(14).

With improved techniques of electrosurgery, several randomized trials - the gold standard of clinical research, were performed. A randomized double blind study (15) performed in 369 patients, showed that diathermy incision is superior compared to scalpel incision with reduced incision time, less blood loss and reduced early postoperative pain. The same advantages have been reported using advanced diathermy technology by Lee et al(16). The mechanism of these positive effects of cutting electrosurgery is that the skin is cut with an electrode delivering pure sinusoidal current, which allows tissue cleavage by rapid cell vaporization without damage to surrounding areas; this may explain the absence of tissue charring and the subsequent healing with minimal scarring (17).

Taking together, the recently published advantages of diathermy in the skin incision could be extremely useful in preventing complications and decreasing maternal morbidity associated with CD. However, there are no clinical trials comparing scalpel and diathermy in the population of pregnant patients undergoing CD. To perform such trials will have direct translational value. In situations of emergency cesarean sections, as an example, it will provide important information on which method will be fastest with the least amount of blood loss.

OBJECTIVE

The objective of this study is to compare scalpel vs. diathermy in abdominal wall incision, in pregnant patients undergoing repeat elective cesarean delivery.



HYPOTHESIS

We hypothesize that the abdominal wall incisions made by diathermy compared to scalpel during repeat cesarean delivery will have less incision time, as well as less blood loss. Further we hypothesize that the use of diathermy, compared with scalpel will not increase post-operative pain.

METHODS

- 1) This is a randomized prospective study in women undergoing elective repeat cesarean delivery or repeat unplanned non-emergent cesarean delivery at Medical Center Hospital in Odessa Texas.
- 2) After informed consent is obtained, women undergoing cesarean delivery will be randomized into two groups:

Group One

Will undergo diathermy to incise the entire abdominal wall, which includes skin, subcutaneous tissue, rectus muscle until the peritoneal cavity is visible.

Group Two

Scalpel will be used to achieve the same aims

- 3) Only patients undergoing elective repeat cesarean delivery will be enrolled, this will decrease the likelihood of introducing bias into the outcome measures, as well as it will make the population more uniform.
- 4) A standardized abdominal wall incision will be made with either diathermy in cut mode or scalpel. Diathermy will be set in a cut mode with standard setting as per surgeon's preference. All patients in the study will get standard skin incision in terms of length and depth which will be marked by a ruler.
- 5) Incision start and stop time will be recorded by a "timer". A digital wall clock in the OR will be used to establish time. The timer will instruct the surgeon to "cut". The timer will record the time. Once the surgeon reaches the abdominal peritoneum, they will announce "stop". The timers will record the time. The incision time will be the difference between the "cut" and "stop" times. These times will be recorded in units of seconds.



- 6) Along the incision depth the bleeding points will be mopped with sponge laps, no suction will be used and total blood loss will be calculated by weighing the laps.
- 7) Blood loss will be recorded as follows: A “used” lap sponge will weighed. A “fresh” lap sponge will be weighed. These weights will be recorded. Blood loss will be calculated as the differences in these two weights. These weights will be recorded in grams.
- 8) As per standard of care spinal or epidural anesthesia will be administered by certified registered nurse anesthetist (CRNA). Post-operative pain will be managed as follows: 1) 300 micrograms of Morphine sulfate will be injected through then spinal needle or epidural catheter at the beginning of the case. 2) 30 milligrams of Toradol will be injected IM, in the left thigh, at the conclusion of the case. 3) 10 mg hydrocodone/325mg acetaminophen 1-2 tablets, per oral, every 4-6 hours, PRN pain.
- 9) Post-operative pain will be measured by a Numeric Pain Rating Scale (see below) scored as 0= no pain, up to 10= worst possible pain. This score will be assessed daily by resident staff at 6:00 to 7:00 AM from post –op day 1 until hospital discharge.
- 10)As per standard MCH protocol, within one hour preoperatively, Ancef 2-3gms will be administered IV. If the patient is Penicillin allergic, she will receive either 900 milligrams of Clindamycin or 1gram of Vancomycin.

OUTCOMES-

Both groups will be assessed for

Primary outcomes:

1. Incision time
2. Blood loss

Secondary outcome:

1. Postoperative pain



SELECTION OF PATIENTS

Inclusion Criteria -

1. Multiparous pregnant women 18 – 45 years.
2. Gestational ages 37 weeks to 41 weeks,
3. Undergoing repeat elective or repeat unplanned non-emergent cesarean deliveries.

Women with medical comorbidities like hypertension, diabetes complicating pregnancy, pregnant women with or without prenatal care, and multiple gestations will also be included.

Exclusion Criteria –

1. Informed consent can't be obtained in a manner that allows for no impression of undue influence/pressure or sufficient time for patient to consider participation.
2. Primary Cesarean deliveries – as these can bias the selection.
3. Skin conditions such as infections, psoriasis, and eczema.

RECRUITMENT PLAN

Patients from University Women's Health Centre (Texas Tech OBGYN clinic) and also from Medical Center Hospital, Odessa, Texas will be recruited. Potential participants will be identified by a member of the study team or clinic/hospital personnel caring for the patient. In the latter case, study personnel will be contacted to meet the patient after the patient has expressed an interest in learning more about participation. All the participants will have the study procedures, risks, benefits and alternatives explained by a member of the study team.

Once informed consent is obtained they will be randomized with 1:1 allocation by a computer generated randomization process. Since the annual rate of cesarean



deliveries in the above-mentioned centers ranges 150 to 175, we expect to enroll a total of 100 patients, and we will allocate 50 patients to each group. Assuming a significance level of 0.05 and a power of 80%, and observing that there is a single measurement and null attrition rate, we will be able to detect at least moderate effect sizes ($d=0.50$) when performing independent means comparisons.

RISKS:

Diathermy –

- A. Possibility of poor wound healing,
- B. There are concerns that large or excessive scars may form,
- C. Unanticipated burns on skin, subcutaneous tissues and other vital organs.

Scalpel –

- A. Injury to the major blood vessels.
- B. Injury to the vital organs.
- C. Excessive bleeding

From the review of recent literature there are some concerns raised regarding the use of diathermy for skin incisions (10, 11, 12). However, we believe that the use of cutting diathermy, as described in our protocol, does not increase patient risk within the study group. First, there is a concern that diathermy, while making skin incisions, may increase the risk of wound complications, as well as delayed wound healing. However these studies differ from ours in a number of ways: A) Most studies claiming increase in risk examine midline abdominal incisions, and our study employs Pfannenstiel skin incision. B) In some studies it is unclear if pure cut mode was employed. The use of a blend mode will cause more lateral spread of current. This may increase the amount of tissue damage, thus promoting wound complications. Our study will employ diathermy only in pure cut mode in a standard setting as per surgeon's preference. A recent Cochrane review, which includes only randomized trials (the highest form of scientific inquiry), found no significant difference in wound complications between scalpel and diathermy (18).



Second, there has been a case report of a severe burn injury on patients back while utilizing diathermy during cesarean delivery (19). The purported mechanism for this burn was an interaction between diathermy and amniotic fluid (19). However in our study, cutting diathermy will be used only in incision of skin, subcutaneous fat and rectus fascia. This use precludes any interaction between diathermy and amniotic fluid.

ADVERSE EVENTS REPORTING:

Any event deemed as an Adverse Event that is possibly related or unexpected to the study will be assessed at each data gathering point and will be reported to the TTUHSC IRB as described in the IRB policies and procedure manual. Monitoring of adverse events will start on the day of surgery.

BENEFITS – There are no guarantees of any benefit to study participants. However, participants may have potential benefits of using electrosurgery which include reducing the amount of blood loss, dry and rapid separation of tissues. For surgeons, there is a reduced risk of accidental cut injuries.

DATA ANALYSIS :

Distributions of operative time, blood loss and post-operative pain will be tested for normal distribution. Student's T test or the non-parametric equivalent will be used to compare these outcomes between the study and control group. Significance level will be set at 0.05.

DATA MONITORING PLAN:

All data for each participant will undergo quality assurance monitoring by personnel not listed as a member of the study team. The purposes of this monitoring are to verify that:

- (a) The rights and well-being of human subjects are protected.
- (b) The reported trial data are accurate, complete, and verifiable from source documents.



(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

RESULTS

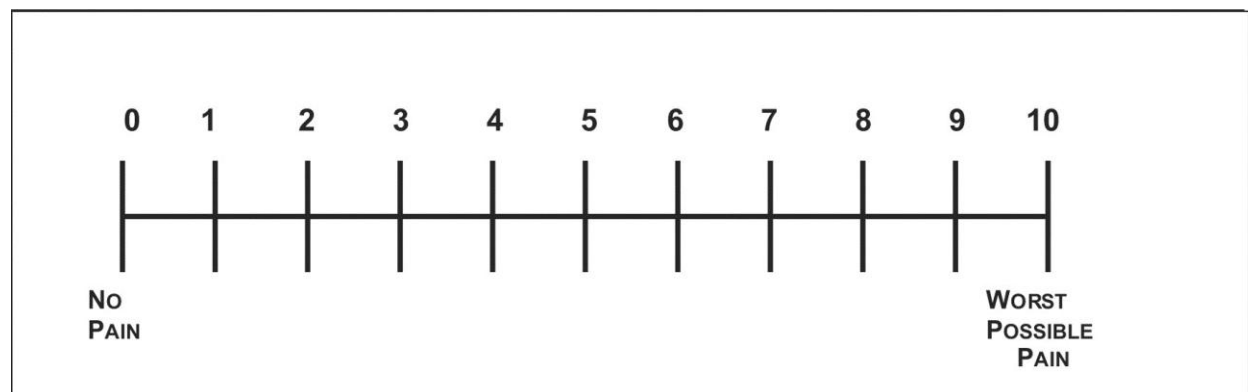
Expected results will be the finding of less operative time, blood loss, postoperative pain, in diathermy abdominal wall incisions compared to scalpel incisions, in pregnant women undergoing repeat cesarean deliveries.

CONCLUSION

To our knowledge, this study will be the first to compare the results of diathermy vs scalpel abdominal wall incisions in pregnant women undergoing cesarean deliveries.

The study results can be used to help determine which method of incision is preferably used especially in case of emergency cesarean deliveries where time is a crucial factor.

Numeric Pain Rating Scale:



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