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Randomized Clinical Trial of Diathermy versus Scalpel in Abdominal Wall Incision during a Repeat Cesarean Section

[2]Martin Caliendo, [2]Leela Sharath Pillarisetty , [2]Eneko Larumbe-Zabala
[1]Department of Obstetrics and Gynecology, Texas Tech University Health Sciences Center Permian Basin, Odessa, TX, USA
[2]Clinical Research Institute, Texas Tech University Health Sciences Lubbock, TX, USA
Corresponding author: Leela Sharath Pillarisetty
Email: drleelasharath@yahoo.com

Abstract

To evaluate if diathermy is superior to scalpel in making abdominal wall incision during repeat cesarean delivery in terms of incision time, blood loss and postoperative pain. A total of 96 pregnant women between 18-45 years, undergoing repeat cesarean delivery between 37-41 weeks gestation were randomized into two groups, one group underwent cesarean delivery with scalpel and the other with diathermy. The primary outcomes of the study is to compare the incision time, blood loss and the secondary outcome is to assess the pain scores between the two groups. A total of 96 women were evaluated and randomized into two groups, there were no differences in sample characteristics. We observed that the incision time using diathermy was significantly shorter, there was no statistical difference in pain assessment. For the blood loss the sample size was smaller and the difference was not statistically significant. Based on these results, we calculated that a sample of 146 subjects in each group would be necessary to show statistically significant differences in blood loss. Compared to scalpel, diathermy can be used to make abdominal wall incisions faster with no difference in blood loss or postoperative pain. We believe the results of this study can be used to support diathermy in making pfannenstiel incisions during some clinical scenarios when time is a critical factor, such as at emergency cesarean delivery the speed of diathermy makes it a superior alternative to scalpel. In situation when blood loss is a concern, such as in Jehovah's Witness diathermy may offer advantages over scalpel.

Keywords

Cesarean delivery, diathermy, scalpel, Incision time

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I. Introduction

In surgery diathermy is most commonly used for dissection of sub-cutaneous fat, peritoneum and fascia, as well as controlling bleeding. Data for their use in making skin incisions is limited [1]. In addition the literature describes advantages, as well as disadvantages for diathermy use in making a skin incision [1-4]. Although it is believed that the advantages outweigh any disadvantage.

Purported disadvantages of electrosurgical skin incisions are fears of deep burns; with resultant scaring, slower wound healing [2], and increased postoperative pain. Lisa et all [3] found a trend toward less incisional blood loss and mentioned that electrosurgical skin incisions are safe and effective. Advantages of diathermy include decreased incision time, blood loss and post-operative pain [4]. Though these data sets are derived from General, Neurologic or plastic surgery, could the same conclusions be extrapolated to an Obstetrical population?

Objective:
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 nor wound complications.

II. Method

This was a Randomized controlled trial performed at Medical Center Hospital in Odessa Texas from July 1st 2015 to May 31st 2016. Inclusion criteria were: 1) Women aged 18-45 years with at least one prior c-section. 2) Gestational age of 37 to 41 weeks. 3) Pfannestiel skin incisions 4) Indication for CD: Elective Repeat CD or Repeat CD in labor. Exclusion criteria: 1) Primary Cesarean sections. 2) Emergency Cesarean Deliveries. 3) Midline vertical skin incisions. 4) Chronic skin conditions such as Psoriasis and Eczema.
A total of 100 patients were enrolled in study. Four were excluded due to a prior midline vertical skin incision.

Based upon a computer - generated 1:1 allocation process 96 patients were randomized into 2 groups, i.e. scalpel or diathermy. Sequential numbered sealed opaque envelopes were used to conceal group assignment. These envelopes were opened just prior to the patient being taken to the OR.

In both groups: 1) Pre-operative: Cefazolin 2gms IV. Penicillin allergic patients received either Clindamycin 900mgs IV or Vancomycin 1gram IV. 2) A Pfannestiel skin incision was made taken down through the subcutaneous tissue, rectus fascia, as well the rectus fascia being dissected of the rectus muscle until the abdominal peritoneum was visualized. 3) Hemostasis was obtained with direct pressure or Bovie set on a standard coagulation mode.

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4) Intra-operative use of 300 micrograms Morphine Sulfate intrathecal followed by 30 mg of Ketolac IM. 5) Post - operative use of Norco 1-2 tablets orally every 4-6 hours PRN.

In the diathermy group, the Bovie pen was set on pure cut mode delivering a 120-watt sinusoidal current. Subcutaneous bleeding was controlled with diathermy on a coagulation mode, as well as utilizing a lap sponge to apply pressure to areas of bleeding.

In the scalpel group an incision was made with a number 22-scalpel blade in a normal fashion. Subcutaneous bleeding was controlled with diathermy on a coagulation mode, as well as utilizing a lap sponge to apply pressure to areas of bleeding.

There were 2 primary outcomes: 1) Incision time. Utilizing a digital wall clock, time was established as follows: When the skin incision was made, the surgeon called out "start the clock". Once the abdominal peritoneum was visualized the surgeon called out "stop the clock". The incision time was the difference between "start" and "stop". 2) Incision blood loss. This was determined as the difference in weight (gm) between a "wet", i.e. used for clearing blood in incision site and a "dry" lap sponge. In the incision site no suction was used.

There were 2 secondary outcomes: 1) Visual Analogue scale (VAS) pain scores from postoperative day (POD) #1 to hospital discharge. 2) Wound complication, defined as infection, bleeding or disruption from POD #1 to hospital discharge.

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III. Data Analysis and Results

Continuous data was summarized as mean (standard deviation) and compared between surgery instruments using Students t-test; type of anesthesia and type of surgery were summarized as frequency (percentage) and compared using chi-squared. Cohen's d was used as a standard measure of effect size for surgery related outcomes. Significance level was set at 0.05.

Table 1

There were no statistically significant differences between groups in sample or demographic characteristics.

	Diathermy (n=48)	Scalpel (n=48)	p
Age (years), mean (SD)	28.4 (5.3)	26.9 (5.1)	0.179
Gravida (n), mean (SD)	3.5 (1.7)	3.1 (1.1)	0.161
Para (n), mean (SD)	1.7 (0.8)	1.7 (0.8)	0.707
Weeks of gestation, mean (SD)	38.4 (1.9)	38.7 (0.7)	0.243
Height (cm), mean (SD)	160 (7.4)	161.5 (7.5)	0.342
Weight (kg), mean (SD)	86.9 (15.1)	85.3 (17.9)	0.639
BMI (kg/m^2), mean (SD)	34.1 (5.7)	32.7 (6.4)	0.273
No. C-sections, mean (SD)	1.7 (0.7)	1.5 (0.7)	0.192
Type of anesthesia, n (%)			0.399
Spinal	46 (95.83)	44 (91.67)	
Epidural	2 (4.17)	4 (8.33)	
Type of surgery, n (%)			0.423
Elective	38 (79.17)	41 (85.42)	
Non-Emergent	10 (20.83)	7 (14.58)	

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TABLE 2

	Diathermy (n=48)	Scalpel (n=48)	p		d
Incision time (s), mean (SD)	188.17 (120.03)	271.5 (109.31)	<0.001		0.73
Blood loss (g), mean (SD)	11.11 (15.43)	15.98 (14.4)	0.113		0.33
VAS score POD 1, mean (SD)	2.6 (3.1)	1.9 (2.6)	0.218		0.25
VAS score POD 2, mean (SD)	2.9 (3.2)	3.2 (3.3)	0.638		0.10

The diathermy technique showed statistically significant shorter incision times, 3minutes 8.2 seconds VS 4 minutes 31.5 seconds with t (94) = 3.56, p < 0.001, d= 0.73. There was a trend for decreased blood loss with diathermy. However, the results were not statistically significant, t (94) = 1.6, p=0.113, as well as the effect size was small d=0.33.

There was no statistically significant difference in VAS. In addition, there were no reported wound complications in either group.

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IV. Discussion

To our knowledge, there is only one other study by Elbohoty et al [5] that compares the diathermy versus scalpel for performing Pfannestiel skin incision in women undergoing repeat cesarean deliveries However based upon methodology differences, we believe our study is unique. The most significant difference is that in both arms of the Elbohoty et al study a scalpel was used to make the skin incision. Other differences: 1) Primary outcome studied was only intra-operative blood loss, 2) Gestational age inclusion criteria was restricted to 38-39 weeks, 3) Assessment of post-op pain was based upon the number of pain pills used, not VAS and 4) Definition of wound complication included skin bruising.

As our results indicate, in repeat Cesarean Deliveries, Pfannestiel Skin incisions performed with diathermy are faster. Although not statistically significant, there was a trend for decreased blood loss in the diathermy group. There were no statistically significant differences found in VAS between scalpel and diathermy. In addition, there were no wound complications described in either group.

One of our primary outcomes, quicker incision time with diathermy is consistent with the findings other studies [5-10]. A multicenter study by Franchi et al did not find diathermy to be faster and states scalpel and diathermy are similar in terms of wound complications [10]. However, that study differed from ours in study population, incision type and surgical procedure.

Although our study demonstrated a trend towards decreased blood, the difference was not statistically significant. This is inconsistent with the results of Elbohoty et.al., as well as Kearns et. al., which demonstrated a significant decrease in blood loss with diathermy [5,10]. Unlike our study, the Elbohoty et. al. was adequately powered to demonstrate a difference. In our study a sample size of 292 (146 scalpel / 146 diathermy) would be required to demonstrate a difference. Kerns et.al. differed in the incision types, procedure performed and study population.

In our study, there was no significant difference in postoperative pain scores between the two groups. Studies by Pearlman et al and Patil et al support this finding [11] [12]. However other studies demonstrate a decrease in post-operative pain scores with diathermy. Within a population of General Surgery patients, Shamim found a decrease in post-operative pain scores [7]. Beside incision type, this differed from ours in patient co-morbidities, patient populations and the method of post-operative pain assessment.

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An unexpected finding was the absence of wound complications in either group. The most likely explanation is that most wound complications, especially wound infections become clinically apparent after discharge from hospital [13]. We did not collect post - hospitalization wound complications information. Due to the transient nature of our patient population, it would be difficult to track that data.

There are limitations to this study: 1) This study was underpowered to demonstrate a difference in one of our primary outcomes, blood loss. 2) A major limitation to our study is the inability to control for differences in surgical skill. Although a 4th year residents performed all operative procedures, there still is variation in each resident's surgical ability. 3) Since diathermy use for skin incision is a common practice at our institution, there may be a bias towards its use. That is compared with scalpel, the residents are much more familiar the use of diathermy in making skin incisions, as well as separating the subcutaneous and fascial layers. 4) We did not examine long term wound complications or pain issues. 5) Satisfaction with cosmetic result was not studied.

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V. Conclusion

In the setting of Repeat Cesarean Delivery, we believe this study supports the use of diathermy in making abdominal wall incisions when compared to Scalpel. When time is a critical factor, such as in an emergency cesarean delivery, the speed of diathermy makes it a superior alternative to scalpel. In situations when blood loss is a concern, for example a Jehovah's Witness diathermy may offer an advantage over scalpel.

CLINICAL TRIAL REGISTRATION:
ClinicalTrials.gov, www.clinicaltrials.gov , NCT02493608.

Disclosure of Interests
The authors have no conflict of interest to disclose.

Contribution to Authorship
The authors responsibilities were as follows: LSP,MC were responsible for designing the study, writing the manuscript and conducting the study; ELZ was responsible for data analysis and editing the manuscript; all the authors are responsible for the final manuscript.

Details of Ethics Approval
The Institutional Review Board of Texas Tech University Health Sciences, Lubbock, Texas, USA approved the study (# L15-144) on May 28, 2015.

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