

Original Research Article

A RANDOMISED CLINICAL TRIAL OF DIATHERMY VS SCALPEL SKIN INCISION IN GENERAL SURGERY

T N Yadav¹, Manish Kumar², Anil Kumar Keshari³, Sohail Ahmad⁴

¹Assistant Professor, Department of Surgery, Madhubani Medical College, Madhubani, Bihar, India.

²Senior resident, Department of Surgery, Madhubani Medical College, Madhubani, Bihar, India.

³Professor, Department of Surgery, Madhubani Medical College, Madhubani, Bihar, India.

⁴Assistant Professor, Department of Surgery, Madhubani Medical College, Madhubani, Bihar, India.

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Corresponding Author:

Dr. Sohail Ahmad

Assistant Professor, Department of Surgery, Madhubani Medical College, Madhubani, Bihar, India.
Email: drsohail2k7@gmail.com.

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ABSTRACT

Background: In an era of explosive anaesthetic agents, electro surgical instruments were used only selectively in human surgery. After the introduction of halothane as an anaesthetic agent, diathermy became increasingly used to control bleeding and for dissection of tissue planes. However, it is still infrequently used for making skin incisions.

Materials and Methods: This was a randomized controlled trial conducted at Madhubani Medical College and Hospital, Madhubani, Bihar from March 2022 to February 2023. It included 250 patients of either sex above the age of five years with general surgical pathology, who were to undergo surgery. Random distribution of patients was done utilizing the blocked method. These patients were divided into blocks of two with scalpel group given block A and diathermy group block B. The first patient was allocated to block A and the second patient to block B. These patients were admitted to the hospitals and a detailed history was obtained from them especially data related to age, sex, co morbid illness, and any previous surgery. All analysis was done using the SPSS software, version 12.0.

Results: A total of 250 patients of different pathologies related to general surgery who completed the follow-up period were finally included in the final analysis. Group A comprised of 133 (50%) patients whose incision was made with a scalpel; including 80 (60.2%) males and 53 (38.8%) females. Mean age of this group of patients was 36.03 years, SD of ± 13.24 years. Amongst the 100 patients of group B whose incision was made with diathermy, there were 85 (85%) males and 15 (15%) females. Mean age of group B patients was 36.52 years, SD ± 12.50 years.

Conclusion: Diathermy incision is a safe and expedient technique. It takes less time than scalpel incision and loss of blood is also lower during incision. Diathermy is associated with lesser post-operative pain and complications than the scalpel incision. Diathermy should be method of choice in general elective surgery.

Keywords: Diathermy; Scalpel; Complications; Pain, Postoperative.

INTRODUCTION

Traditionally scalpels are used for making skin incisions that produce little damage to surrounding tissues.^[1] However, there has been a continuous surge in identifying other methods of skin incision and in the recent years electro surgical instruments have achieved great attention in this regard. There has been a widespread use of diathermy for

homeostasis but fear of production of large scars and improper tissue healing has restricted their usage in making skin incisions.^[2,3] Electrodes used in making diathermy incision generate a pure sinusoidal current, which produces cleavage in tissue planes without creating damage to the surrounding areas. This is one of the reasons of less damage inflicted to the tissues leading to minimal scar formation.^[2,4] At the same time, use of diathermy in skin incisions reduces bleeding and makes the incision quicker.^[5]

but there are no differences in wound burst strength. Previously, it has been reported that there is a greater rate of infection with diathermy incisions than with scalpel incisions.^[6] Many studies in the past have evaluated perioperative blood loss, postoperative wound pain and wound healing in a selected group of patients, mainly with midline laparotomy incisions.^[4,7] There have been limited studies comparing diathermy incisions with conventional scalpel incisions amongst all types of elective surgical procedures.

Aims and Objective

This study focused on all general surgical operations and compared incisional time, blood loss during incision making, postoperative pain and wound complications for both methods of skin incision.

MATERIAL AND METHODS

This was a randomized controlled trial conducted at Madhubani Medical College and Hospital, Madhubani, Bihar from March 2022 to February 2023. It included all patients of either sex above the age of five years with general surgical pathology, who were to undergo surgery. Patients aged less than five years, with serious co morbid illnesses like severe cardiac (ASA-3) or airway disease or liver disease were excluded. Also patients who presented in acute surgical illnesses with gross infection found at operative site were excluded. Patients who did not attend follow-up sessions were also excluded from the final analysis.

Random distribution of patients was done utilizing the blocked method. These patients were divided into blocks of two with scalpel group given block A and diathermy group block B. The first patient was allocated to block A and the second patient to block B. These patients were admitted to the hospitals and a detailed history was obtained from them especially data related to age, sex, co morbid illness, and any previous surgery. Thorough examination was conducted to determine variables such as general health, weight, anemia, jaundice and any previous scars. Investigations for general fitness, including variables such as blood Complete Picture (Blood CP), blood sugar and blood urea, were performed. When required electrocardiogram (ECG) and chest x-ray were also performed for the same purpose. In addition, investigations like ultrasound, CT-scan, intravenous urography, gastroduodenoscopy, contrast studies of gut, thyroid scan, mammography and fine needle aspiration cytology (FNAC) were performed to establish diagnosis. Patients were briefed about the diagnosis and procedure to be performed. Those who met the eligibility criteria were invited to participate in the study and were informed about both methods of skin incisions. Advantages and disadvantages of both types of incisions were explained and permission was granted from the patients. Those who refused were not enrolled in the study and those who consented to

participate were enrolled and assured that their participation is voluntary with no harms to them in terms of getting due treatment. They were also given the right to withdraw from the study without any reason.

Standard prophylactic antibiotics were given to all patients according to the site of injury and patient's age at the time of induction of anaesthesia, and were continued for one to three days depending on the type of surgery. Skin and subcutaneous tissue was incised with a surgical blade for group A patients and with diathermy for group B patients. Haemostasis was secured with the coagulation mode of diathermy or with ligatures. An electrosurgical instrument brand Valley lab force 40 was used for the entire study. It was set at 417 KHz sinusoidal current. The instrument was checked and calibrated periodically according to service manual guidelines, by the bio-medical engineering department.

There was more than one observer during the whole study period. Different interns were trained and allocated to observe different components of the process and record the data for each individual patient. Each intern recorded data on one variable and only one observer was allocated to single variable. Subcutaneous tissue was closed with chromic 2/0 interrupted stitches and skin stitches were applied in a subcuticular pattern with Prolene 2/0. Postoperatively both groups of patients received intramuscular diclofenac sodium three times a day supplemented by intravascular infusion of tramadol as necessary. As patients tolerated oral feeding well they were shifted to oral diclofenac sodium three times daily. In none of the patients subcutaneous drains were placed.

As patients tolerated oral feeding and became mobile they were discharged from the hospital. The wound was checked on the fifth postoperative day if the patient had remained in the hospital. It was checked earlier when the dressing of the patient became soaked or the patient developed fever or tachycardia with no other source of fever or tachycardia noticed. Patients were advised to attend outpatient clinics for removal of stitches on the 10th postoperative day. Follow-up visits were advised at one, three and six months.

Sample size was calculated using the G-Power software version 3.0.10; with an effect size of 0.4 and 95% power at 5% level of significance, a total sample of 250 patients were required with 125 participants in each group. All this data was recorded on a pro forma. Data was calculated and analyzed for categorical and continuous variables such as age, sex, co morbid illness, incisional time, blood loss during incision making and postoperative pain and wound complications for both methods of skin incision. Incision time, blood loss during incision making and postoperative wound pain were analyzed with Student's t-test and wound complications were compared for the two groups using the chi-square test. P values of less than 0.05 were considered

significant. All analysis was done using the SPSS software, version 12.0.

The tested hypothesis was that skin incision with a conventional surgical blade has better results in terms of the above-mentioned variables than diathermy incision. Incision time was calculated from the start of skin incision until deep fascia, aponeurosis or lump reached with complete haemostasis. Incision length and depth was measured using sterilized calibrated scales. Blood loss during incision was measured weighing the swabs pre and postoperatively. Wound pain was calculated by the verbal rating score (VRS). Wound healing was classified using the Southampton wound grading system; G0: normal wound healing, G1: normal healing with mild bruising or erythema, G2: erythema plus other signs of inflammation, G3: clear or serosanguinous discharge, and G4: Purulent discharge.

RESULTS

A total of 250 patients of different pathologies related to general surgery who completed the follow-up period were finally included in the final analysis. Group A comprised of 133 (50%) patients whose incision was made with a scalpel; including 80 (60.2%) males and 53 (38.8%) females. Mean age of this group of patients was 36.03 years, SD of ± 13.24 years. Amongst the 100 patients of group B whose incision was made with diathermy, there were 85 (85%) males and 15 (15%) females. Mean age of group B patients was 36.52 years, SD ± 12.50 years. The total numbers of male and female patients were 165 and 68, respectively, making a 1.44:1.00 ratio. The most common operations performed in this study was on the kidneys and upper ureters, performed on 75 (28.65%) patients,

followed by 60 (25.15%) patients of hernias. [Table 1]

Co morbid illnesses were noticed in 22 (14.78%) and 25 (17.18%) patients of group A and B, respectively. Their distribution was as follows; Group A: diabetes mellitus (DM): 14 (12.11%), hypertension (HTN): one (0.5%), both DM and HTN: three (1.1%), chronic obstructive pulmonary disease (COPD): four (1.7%), chronic liver disease (CLD): one (0.4%); Group B: DM: 15 (10.1%), HTN 1 (1.2%), Both DM and HTN: 3 (2.4%), COPD: 1 (1.1%). We compared the two groups for baseline characters such as age, sex and presence of co morbid conditions and the groups were similar with respect to these variables as no statistically significant difference was found.

Mean incision time was 9.8014 sec/cm² (SD ± 1.2444 sec/cm²) for group A and 6.2046 sec/cm² (SD ± 0.8566 sec/cm²) for group B patients. Similarly mean incision blood loss was also found to be significantly higher in group A i.e. 1.711 mL/cm² (SD ± 0.1873 mL/cm²) compared to 1.1235 mL/cm² (SD ± 0.2288 mL/cm²) in group B patients. Postoperative pain was assessed by VRS on day one, two, and five. It was significantly higher in group A. Mean hospital stay was 51.7830 (SD ± 34.006) hours in group A and 45.5320 (SD ± 31.1252) hours among group B patients. This difference was also statistically significant. Among wound complications, 24 (16.16%) patients from group A and 20 (13.51%) patients from group B developed wound complications. Erythema of wound margin (G: 1) was found in eight (4.5%) patients of group A and four (1.7%) patients of group B. Overall no statistically significant differences were seen regarding wound complications for the two groups.

Table 1: Pathological Viscera Found in the Study (n = 250)

Kidneys and upper ureters	36 (24.9)	29 (29.7)	65 (28.65)
Hernias	29 (20.3)	22 (29.2)	51 (25.15)
Gall bladder and biliary tree	20 (17.4)	13 (14.6)	33 (14.54)
Lower ureters, urinary bladder and prostate	13 (8.9)	10 (6.8)	23 (8.18)
Surface swelling	11 (9.3)	8 (6.1)	19 (6.66)
Gastrointestinal tract	9 (6.0)	5(5.0)	14 (5.006)
Scrotal pathology	5 (3.1)	4 (2.4)	9 (2.77)
Thyroid pathology	4 (4.3)	2 (2.2)	6 (2.38)
Breast pathology	3 (2.6)	2(2.2)	5 (2.74)
Uterine and ovarian pathology	2(2.2)	3 (2.7)	5 (2.74)
Retro peritoneal mass	2 (2.1)	1 (1.2)	3 (1.31)
Total	133	100	233

DISCUSSION

In an era of explosive anaesthetic agents, electro surgical instruments were used only selectively in human surgery. After the introduction of halothane as an anaesthetic agent, diathermy became increasingly used to control bleeding and for

dissection of tissue planes. However, it is still infrequently used for making skin incisions. The reluctance in the use of skin incision is due to the fear that electro surgical instruments create increased amounts of necrotic tissue within the wound which may increase the chances of wound infection leading to delayed wound healing and excessive scarring.^[2,8-10]

After the introduction of oscillator units, which produce pure sinusoidal current, there has been an increasing trend in the use of diathermy for making skin incisions. In the recent years, many studies have been conducted on both methods of skin incision, which showed less operating time, diminished loss of blood, and reduced early pain and fewer requirements of analgesic drugs after surgery using the diathermy method of skin incision when compared to scalpel incision.^[2] In one experimental study, conducted on rats, it was shown that wound incisions made with a cold scalpel had more rapid tensile strengths as compared to diathermy or harmonic scalpels.^[8]

Ly et al,^[11] in their systemic review and meta-analysis of fourteen randomized trials comprising of 2541 patients (1267 undergoing skin incision by cutting diathermy and 1274 by scalpel), found that diathermy may offer significant advantages in many variables including, operative blood loss, incision time and postoperative pain. They noticed significantly reduced amounts of blood loss (mean difference of 0.72 mL/cm (2); $P < 0.001$) and shorter incision times (mean difference of 36 seconds; $P < 0.001$) with diathermy incisions as compared to scalpel incisions.

In our study, diathermy mode of skin incision took less time and led to less loss of blood i.e. 6.2046 sec/cm² and 1.1235 mL/cm², respectively compared to scalpel incisions in which measurement of these variables were 7.8014 sec/cm² and 1.7151 mL/cm², respectively. These findings are consistent with findings reported by Ly et al. and another local study. In a study by Shamim M,^[3] incision time was 5.1342 sec/cm² and incisional blood loss was 1.64 mL/cm² in the scalpel group, which was shorter than our study.

In the study by Aird et al,^[12] from Canada, they performed a systematic electronic literature search using two electronic databases (MEDLINE and PubMed), and the methodological quality of included publications was evaluated. Six randomized control trials (RCTs), which compared the electrocautery method of skin incision (n = 606) with scalpel incision (n = 628), were analyzed. They noticed less incisional blood loss and reduced operating time with the electrocautery method of skin incision. Gilmore and colleagues,^[13] at Dublin, Ireland, compared diathermy and scalpel incisions for hemiarthroplasty. In their study certain variables such as age, sex and pre-operative aspirin use were similar in both groups. Scalpel incisions produced per operative blood loss, which was over 30% of the total operative blood loss as compared to 18.5% in incisions made with diathermy.

Chalya et al,^[14] in their study on diathermy versus scalpel incisions in elective midline laparotomy at Tanzania showed the mean incision time with scalpel was 9.21 ± 1.40 sec/cm² in comparison to 7.84 ± 0.82 sec/cm² with diathermy incisions. The difference between the two groups with respect to the mean incision time was statistically significant (P

= 0.001). The mean loss of blood was 1.62 ± 0.14 mL/cm² for scalpel incisions and 1.12 ± 0.20 mL/cm² for diathermy incisions thus significantly less bleeding was noticed with diathermy incisions ($P = 0.012$).

Elective midline laparotomy incisions made with diathermy have significant benefits over scalpel incisions in terms of decreased incision time and reduced blood loss as shown in many studies performed by Siraj et al,^[10] Gilmore et al,^[13] and Shiva gouda et al.^[15] In his study Sheikh,^[16] noticed significantly shorter incision times and reduced blood loss in diathermy skin incisions. In one study by Kearns and colleagues,^[2] it was found that diathermy produces significantly less postoperative pain on the first and second postoperative day when compared to scalpel incisions. From the third postoperative day onwards, severity of pain after surgery became significantly different between the two groups. In this study postoperative pain on the first and second postoperative days was higher in the scalpel group (i.e. 5.2957 and 2.1049) when compared to the diathermy group (3.1181 and 1.6206). There was no significant difference in pain of both groups on subsequent days.

Chrysos et al,^[17] in their prospective study comparing diathermy and scalpel incisions in tension free inguinal hernioplasty noted lower VRS with diathermy incisions during the initial two postoperative days. They found that immediate tissue and nerve necrosis with diathermy might be due to cell vaporization, which doesn't significantly affect the nearby structures. Chalya et al,^[14] revealed significantly reduced mean VAS with diathermy incisions as compared to scalpel incisions on postoperative day one ($P = 0.001$), two ($P = 0.011$) and three ($P = 0.021$). Intramuscular analgesic requirements were also significantly lower with diathermy incisions than scalpel incisions ($P = 0.021$). The difference between the two groups was not statistically significant ($P = 0.243$).

In their study Aird et al,^[12] noted that electrocautery significantly reduced postoperative wound pain. Results of our study are consistent with other studies by Siraj et al,^[10] Gilmore et al,^[13] and Shiva Gouda et al,^[15] which showed that elective midline laparotomy incisions made with diathermy had significant benefits compared to scalpel incisions in terms of reduced early postoperative pain and analgesic requirements.

In our study, postoperative wound complications were slightly higher in patients of the scalpel group (17.17%) than diathermy group (14.61%). Similar results were reported by Kearns et al,^[2] Shamim,^[3] and Chrysos et al.^[17] In the study of Franchi et al,^[18] on gynaecological oncological patients demonstrated that scalpel incisions produced severe wound complications in a greater number of patients as compared to incisions made by electrocautery (8.531 vs. 1.433, $P = 0.05$). However, after adjustment of confounding variables like age and body mass index

there was no difference in wound complications between the two groups.

Eren et al.^[19] from Istanbul compared wound complications associated with scalpel and electrocautery in patients operated for gastrointestinal malignancies with different incision methods. Their study revealed no significant statistical difference in wound infection or incisional hernia between the two groups ($P > 0.05$). Therefore, in their study the choice of incision method depended upon the surgeon's preference. In their study Aird and colleagues,^[12] noticed no significant difference in wound infection or scar formation between the two methods of skin incision. None of the patient in both groups developed wound infection or dehiscence as reported by Gilmore and their colleagues.^[13] However wound oozing was noticed in the scalpel group in four patients that were treated conservatively. Post-operative complications were not significantly different amongst the two groups as reported by the study of Chalya et al.^[14]

Groot and Chappell,^[20] noticed wound infections in 15% (38/250) of patients when incision was made by a scalpel and in 12% (30/342) of patients with incisions made by cautery. They noticed no difference in wound infections amongst patients of different age and genders, level of obesity, those using steroids and cases with diabetes. Also duration of preoperative stay at the hospital, duration of surgery, prophylactic usage of antibiotics and presence of drains produced no significant difference in wound infection of both groups. Chalya et al,^[14] reported that the mean length of hospital stay (LOS) in both groups was 14.63 ± 6.36 (scalpel group 12.34 ± 34 and diathermy group 11.78 ± 6.48 days). The mean LOS did not differ significantly between the two groups ($P = 0.834$). This data shows that electrocautery has significant advantages in creating incisions in surgery patients. The surgeon must be properly trained and thoroughly familiar with the effects of local wound environment on healing.^[21]

Further, increased prevalence of blood borne diseases like hepatitis C and HIV infection favour the use of electrocautery in skin incisions thereby keeps the scalpel away from the operative field.^[2] Our study is one of the few attempts towards comparing the effectiveness of the two incision techniques. We included participants from two different cities and included both public and private health facilities, which provided us with a diverse group of participants. We assigned observers for specific measurements, which add to the accuracy of the results as assigning multiple measurements at the time of procedure to one individual could influence their observations.

CONCLUSION

Electrosurgical incision is safe for both patients as well as for surgeon. It requires less time, there is less blood loss during skin incisions, and produces decreased postoperative pain and wound complications. At the same time there are a significant number of Hepatitis B and C patients who require surgery. The use of electrocautery in skin incision keeps scalpels away from the operative field thereby decreasing chances of transmission of these and other lethal diseases to the operating team.

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