



A PROSPECTIVE RANDOMIZED CONTROL STUDY OF SCALPEL AND SURGICAL DIATHERMY INCISION IN ELECTIVE OPERATIONS

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ABSTRACT

Incision has always been an integral part of surgery. Very few operations can be performed without cutting through the skin. It may be incised to gain access to deeper structures, or the surgery may be primarily on the skin itself whether for the repair of trauma or for the excision of a skin lesion. Traditionally scalpels with disposable knives are used for skin incisions. Electro cautery has been used less frequently because of the fear of tissue damage leading to more postoperative pain, impaired wound healing and hypertrophic scarring. Pain is one of the common complications of any surgery that troubles the patient in the immediate post-operative period and can increase patient's morbidity [14]. A good pain control will not only alleviate patient's distress but lead to reduced stress response, important in patients with compromised cardiovascular functions. Pain relief is imperative as it lightens patient's anxiety and helps in rapid uncomplicated recovery. The severity of post-operative pain is influenced by numerous factors such as anaesthesia, analgesia and the technique of surgery, including the method of incision of tissues. Scalpel or diathermy abdominal incisions are the two ways of accessing the abdominal cavity. Traditionally, the most common method of making the incision is by using the scalpel. But over the years with the easy availability, lessened bleeding and minimized risk of superficial infections, diathermy is gaining popularity. The use of thermal energy, of either type, raises concerns about collateral heat damage, impaired wound healing and a possible increased risk of wound infection secondary to necrosis at the wound edges. Studies conducted in humans and animals have provided different results. This leads to my research question that does the use of surgical diathermy for making incision in open surgeries for inguinal hernia in adults result in lesser rates of incision time / incision haemorrhage / post operative pain / wound complications as compared to the use of a surgical knife for the incision.

KEYWORDS : Incision, Scalpel, Diathermy

INTRODUCTION

Incision has always been an integral part of surgery. Very few operations can be performed without cutting through the skin. It may be incised to gain access to deeper structures, or the surgery may be primarily on the skin itself whether for the repair of trauma or for the excision of a skin lesion. Skin bleeding is the problem after starting surgery.⁽¹⁰⁾

Traditionally scalpels with disposable knives are used for skin incisions. Electro cautery has been used less frequently because of the fear of tissue damage leading to more postoperative pain, impaired wound healing and hypertrophic scarring. Surgical diathermy is used frequently in the operating room.⁽¹¹⁾

In principle, diathermy uses the heating effect of an electrical current across a resistor. In practice, the "resistor" is the patient's skin or other tissue being cauterized or cut. Alternating current (AC) is often used in clinical practice. The correct term for resistance with AC as opposed to direct current (DC) is impedance. A potential difference created by the diathermy device produces a current that passes through the patient to complete an electrical circuit. This circuit may be completed in two ways:

a) Unipolar diathermy: The cathode (–) is the cautery-diathermy (Bovie) tool tip, and the anode (+) is the ground or return plate which is usually located on one of the patient's buttocks or thighs. Unipolar diathermy-cautery configurations have the highest potential for complications, because the current pathway between the cathode and anode may pass near or across the pulse generator or leads.

b) Bipolar diathermy: Both the cathode (–) and the anode (+) are incorporated in a forceps and are therefore very closely spaced. Thus, a grounding plate is not required with bipolar diathermy-cautery, and the current pathway is very small. The risk of CRMD-related complications is much smaller (but not absent) because the current pathway is far less likely to pass near or across the pulse generator or leads. The exception is if cautery is applied directly to or very near (i.e., within a few centimeters) the pulse generator or leads.

Diathermy units often develop power levels between 50 and 400 watts and radiofrequency AC cycles from 300 kHz to 3 MHz. Current is delivered in varying waveform patterns or modes. Continuous current is used for cutting, and pulses are used for coagulation. Because the pure cutting (diathermy) mode uses continuous current, it produces a series of sparks from the diathermy tool to the tissue. The pencil tip does not have to contact the tissue. The sparks generated cause intense local heating of cellular water, causing cellular explosion and destruction over a narrow band. In contrast, coagulation (cautery) requires the direct application of the pencil tip; heat is thus dissipated

over a wider area, causing the cells to shrink (crenate) and dry out (desiccate) rather than explode.

Bipolar diathermy is generally restricted to coagulation modes. In contrast, unipolar diathermy incorporates coagulation and cutting.

a) In the cutting mode, a continuous current rapidly produces extreme heat causing intracellular water to boil and cells to explode into steam (vaporization). By moving the electrode quickly, more cells vaporize and the tissue is divided with minimal devitalized or charred tissue left along the margin of the cut surface. Thermal damage is kept to a minimum because heat is lost through evaporation of the steam and is not conducted through the cut tissues, which would dry out the adjacent cells. As the electrode is moved forward, new cells are contacted and vaporized with the creation of the incision. This may explain the absence of tissue charring and the subsequent healing of tissues with minimal scarring.

b) In the coagulating mode, short bursts of electrical current are applied with a pause between each burst. As a result, the heat produced in the cells dries up the tissue but is not intense enough to evaporate intracellular water. The coagulating mode results in a greater degree of thermal damage and necrosis of adjacent tissues.

Pain is one of the common complications of any surgery that troubles the patient in the immediate post-operative period and can increase patient's morbidity⁽¹⁴⁾. A good pain control will not only alleviate patient's distress but lead to reduced stress response, important in patients with compromised cardiovascular functions. Pain relief is imperative as it lightens patient's anxiety and helps in rapid uncomplicated recovery. The severity of post-operative pain is influenced by numerous factors such as anaesthesia, analgesia and the technique of surgery, including the method of incision of tissues.

Scalpel or diathermy abdominal incisions are the two ways of accessing the abdominal cavity. Traditionally, the most common method of making the incision is by using the scalpel. But over the years with the easy availability, lessened bleeding and minimized risk of superficial infections, diathermy is gaining popularity.

The use of thermal energy, of either type, raises concerns about collateral heat damage, impaired wound healing and a possible increased risk of wound infection secondary to necrosis at the wound edges.

Studies conducted in humans and animals have provided different results.

This leads to my research question that does the use of surgical

diathermy for making incision in open surgeries for inguinal hernia in adults result in lesser rates of incision time / incision haemorrhage / post operative pain / wound complications as compared to the use of a surgical knife for the incision.

AIM AND OBJECTIVES

AIM OF THE STUDY

A prospective randomized double blinded control study of scalpel and surgical diathermy skin incision in elective operations.

OBJECTIVES OF THE STUDY

The objectives of this study was to examine, following parameters between the study groups.

- incision time
- blood loss during incision
- post-operative pain
- Post-operative wound complications and wound healing

MATERIALS AND METHODS

This prospective randomised control study was conducted at Lisie Hospital from 1st august 2019 to 31st January 2020 on patients who presented with inguinal hernia, planning for hernia repair.

1. **STUDY AREA:** Lisie hospital, Ernakulam, Kerala. All patients coming from Ernakulam city and nearby villages, giving consent for study, were included.

2. **SOURCE OF DATA AND STUDY POPULATION:** This randomised controlled trial was done in the Department of General Surgery, Lisie hospital outpatient department presenting with inguinal hernia.

3. **DESIGN OF THE STUDY:** Randomized Controlled Study

4. **SAMPLE SIZE:** 130

5. **SAMPLING METHOD :** Randomization is done by computer generated random number table, odd numbers are assigned to group A {steel scalpel} and even numbers to group B {surgical diathermy}.

6. DETERMINATION OF SAMPLE SIZE

Sample size is calculated using the formula

$$n = \frac{2Sp^2 [Z_{1-\alpha/2} + Z_{1-\beta}]^2}{\mu d^2}$$

$$Sp^2 = \frac{s_1^2 + s_2^2}{2}$$

n = sample size

So the minimum sample size required for the study is 63 in each group It is taken as 65

So n=130

Period Of Study: 1st August 2019 to 31st January 2020

Inclusion And Exclusion Criteria

Inclusion Criteria

Patients presenting to Lisie general surgery department with inguinal hernia in the age group of 20-80 years planning for hernia repair, giving consent for the study.

Exclusion Criteria

- Over previous scar in the groin {recurrent hernias}
- Anticoagulant therapy
- DM {uncontrolled, HbA1c > 7.5} and HTN {uncontrolled- systolic > 180, diastolic > 90, in 2 consecutive readings}
- Pregnancy
- Immunocompromised- {on steroid therapy, other diseases}
- Emergency {irreducible/obstructed/strangulated}
- Severe organ dysfunction {end stage renal disease/decompensated liver disease/CAD-EF < 50 %}
- Patient not willing to give informed consent

METHODS OF COLLECTION OF DATA

- The study was approved from the Ethical and Research Committee, Lisie Medical Institute, Ernakulam.
- Patient will be selected in the age group of 20 -80 years presenting to opd with inguinal hernia, planning for hernia repair. The eligible patients who fulfilled the selection criteria were informed in detail about the nature of the study and a written informed consent was

obtained (Annexure I).

- Patient and the evaluator are blinded. {Evaluator is a surgery resident who is not involved in the study, will be evaluating the patient on table, post operatively and on follow up}
- Preop skin wash & skin preparation as per institution protocol's {all patients will have to undergo a body bath with medicated soap on the previous day and on the day of surgery, betadine for skin preparation}
- Preop antibiotic- Third generation cephalosporins
- Knife size 10/22
- Cautery –cutting pure / blend at setting of 30

Incisional time- {Incision time is defined as the time from the beginning of skin incision until subcutaneous tissue is reached with complete hemostasis} it is expressed in seconds⁽⁶⁾

Incisional haemorrhage- It is assessed using one single gauze {by measuring the weight of swabs used exclusively during incision until complete hemostasis is achieved⁽⁶⁾.

Wound closure- Subcuticular stitches {3-0 nylon}

Pain- Assessment according to pain scale {numerical} The pain assessment was done by surgery resident at fixed times on postoperative days 1, 2 and 3 using the verbal, numerical rating scale to assess the level of pain⁽⁶⁾.

Post operative analgesia- A combination of tramadol hydrochloride (50mg) and paracetamol (325mg)

FOLLOW UP

Patients are followed up for 4 weeks, assessment was done as follows

- Evaluation of pain from POD 1 onwards to POD 3 {assessed using numerical pain scale of 1-10}
- Patient discharged on POD 3, Advised to review after 1 week
- Review on POD 10- wound inspection and suture removal {wound healing/complications assessed}
- Review on POD- 30 – wound inspection {wound healing/complications assessed}
- Patients are advised to come to opd if any signs of wound infection {serous /pus discharge, swelling, redness} or wound gaping in between the days of 10-30. Otherwise review on POD 30.

Statistical Analysis

- The data will be entered into excel worksheet and analysis performed using **spss23**. Normality of data will be tested using **Shapiro-wilk** test.
- Incision time for procedure, blood loss for procedure and pain score difference in two groups will be analyzed using unpaired **t** test.
- The difference of wound complication will be analyzed by **chi-square** test.

OBSERVATION AND RESULTS

A total of 130 patients were included in the final analysis. Patients were divided into two groups each, group A- steel scalpel, group B- surgical diathermy.

Table 1. Age Distribution Of The Study Population {N=65}

Age	Group		Total
	Steel Scalpel {A}	Surgical diathermy {B}	
21-30	8	4	11
31-40	7	1	8
41-50	7	8	15
51-60	14	21	35
61-70	24	23	47
>70	5	8	13
Total	65	65	130

In this present study a total of 130 patients were involved, with N=65. Group A is steel scalpel and group B is surgical diathermy. In which maximum number of patients were enrolled in age group of 61-70 yrs, minimum in age group of 31-40 yrs.

Table 2. Comparison Of Mean Age (years) Between Study Groups (N=65)

Group	Mean	Standard Deviation	Student t test value	P value

Steel scalpel{A}	53.55	15.252	1.762	0.080
Surgical diathermy{B}	57.83	12.257		

In the present study the mean age in group A was slightly lower (53.55±15.252 years) compared to group B (57.83 ± 12.257 years) but difference was statistically not significant (p=0.080).

Table 3.comparison Of Incision Time {inseconds} Between Study Groups {N=65}

Group	Mean	Standard Deviation	Student t test value	P value
Steel scalpel {A}	20.146154	2.7015665	24.081	.0001
Surgical diathermy {B}	11.493846	1.0453583		

In the present study mean incision time in group A was 20.1461 ± 2.70 seconds and group B was 11.4938±1.04 seconds. The incision time was significantly higher in patients in scalpel group compared to surgical diathermy group (P=0.0001).

Table 4. Comparison Of Incision Hemorrhage {in Grams} Between Study Groups {N=65}

Group	Mean	Standard Deviation	Student t test value	P value
Steel scalpel{A}	5.253846	.7254475	28.320	.0001
Surgical diathermy {B}	2.369231	.3848389		

In this present study blood loss during incision was 5.25 ± 0.725 gms and 2.36 ± 0.38gms ,in group A and B respectively .Incision haemorrhage was significantly higher in steel scalpel group compared to diathermy , and was statistically significant {p - 0.0001}

Table 5. Comparison Of Pain Score In Post Operative Day- 1 Between Study Groups {N=65}

Group	Mean	Standard Deviation	Student t test value	P value
Steel scalpel{A}	6.40	.766	21.6	0.0001
Surgical diathermy {B}	2.86	1.074		

Comparison between pain in post operative day 1 in study groups A and B was 6.40 ± 0.766 an 2.86 ± 1.074 respectively .results showed very less pain in group B, and was statistically significant {p-0.0001}

Table 6. Comparison Of Pain Score In Post Operative Day- 2 Between Study Groups {N=65}

Group	Mean	Standard Deviation	Student t test value	P value
Steel scalpel{A}	4.92	.872	27.82	0.0001
Surgical diathermy {B}	1.12	.673		

Comparison between pain score in post operative day 2 in study groups A and B was 4.92 ± 0.872 and 1.12 ± 0.673 respectively .Pain was significantly less in diathermy group compared to steel scalpel group {p-0.0001}.

Table 7. Comparison of pain score in post operative day- 3 between study groups {N=65}

Group	Mean	Standard Deviation	Student t test value	P value
Steel scalpel{A}	3.71	.843	23.056	0.0001
Surgical diathermy {B}	.62	.678		

Comparison between pain score in post operative day 3 in study groups A and B was 3.71 ± 0.843 and 0.62 ± 0.678 respectively .Pain was significantly less in surgical diathermy group compared to steel scalpel group {p-0.0001}

Table 8. Wound Examination On Post Operative Day 10 In Study Groups{N=65}

Southampton scoring	Group		Total	P value (Chi square)
	Steel Scalpel{A}	Surgical diathermy {B}		
0	61	62	123	0.779
1a	2	2	4	
1c	1	1	2	
2c	1	0	1	
Total	65	65	130	

On comparing the two study groups on post operative day 10 ,according to southampton scoring system ,it was found to have normal healing {Score- 0} in 61 patients of group A and 62 patients in group B.

There was found to have some bruising { score 1a}, 2 patients in each group. Mild erythema {score 1c} noted 1 patient of both the group. Erythema along with rise in skin temperature noted along the length of the wound {score 2c} in a patient of group A. But all these results were statistically insignificant {p=0.779}.

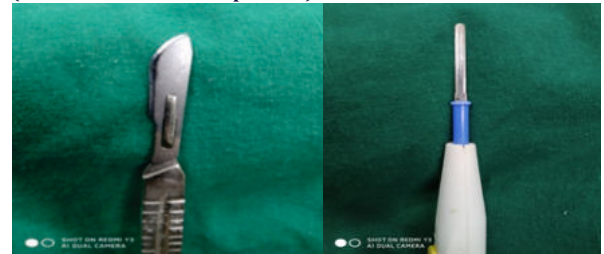
Table 9. Wound Examination On Post Operative Day- 30 In Study Groups {n=65}

Southampton scoring	Group		Total
	Steel Scalpel{A}	Surgical diathermy {B}	
Score -0	65	65	130
total	65	65	130

Comparison between wound healing between study groups on post operative day 30 , revealed , a score of zero { normal healing } according to Southampton grading system.

PHOTOS

{obtained from different patients}

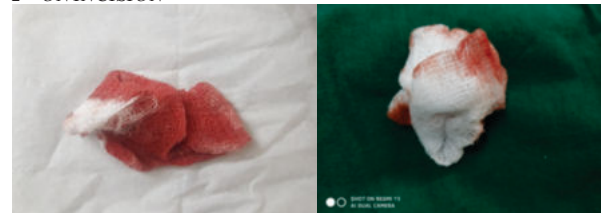


GROUP A
STEEL SCALPEL-BLADE 10
1.INSTRUMENTS USED

GROUP B
CAUTERY TIP



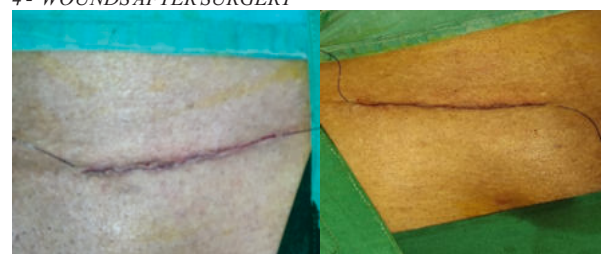
2- ON INCISION



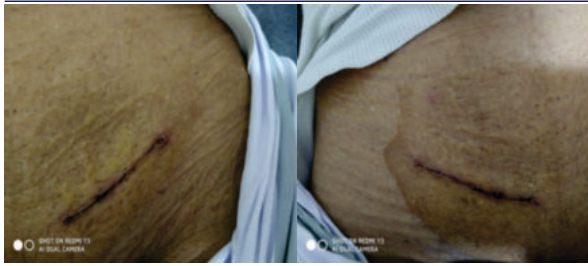
3-BLEEDING MEASURED IN A SWAB



4- WOUNDS AFTER SURGERY



5-WOUNDS AFTER SUTURING {3-0 nylon subcuticular stitches}



6-WOUNDS ON POST OPERATIVE DAY 10

DISCUSSION

The numbers of patients studied were 130 and randomly divided into two test groups of 65 each. Both groups were matched {Group A – Steel scalpel, Group B- Surgical diathermy }

1. Incision Time

In our study mean incision time in group A was 20.1461 ± 2.70 seconds and group B was 11.4938 ± 1.04 seconds. The incision time was significantly higher in patients in scalpel group compared to diathermy group ($P < 0.0001$).

Table 10 Comparison Of Incision Time Between Various Study Groups

GROUP	Present study	Noopur Priya et al	Talpur et al
A	20.1461 ± 2.70	55.54 ± 22.24	8.9025-sec/cm2
B	11.4938 ± 1.04	28.58 ± 18.90	7.3057 sec/cm2

These findings were consistent with study conducted by **noopr priya et al**^[3] in 2017 as the results showed mean incision time {in seconds} in scalpel group was 55.54 ± 22.24 and in surgical diathermy group was 28.58 ± 18.90 . And a study conducted by **Talpur et al**^[10] in 2015, in which the mean incision time was 8.9025-sec/cm2 and 7.3057 sec/cm2 in steel scalpel and electrocautery group respectively. Our present study results were in accordance with the above two studies.

2. Incision Haemorrhage

In this present study blood loss during incision was 5.25 ± 0.725 gms and 2.36 ± 0.38 gms, in group A and B respectively. Incision haemorrhage was significantly higher in steel scalpel group compared to surgical diathermy, and was statistically significant ($p < 0.0001$).

Table 11 Comparison Of Incision Haemorrhage In Various Study Groups

Group	Present study	Noopur Priya et al {ml}	Talpur et al
A	5.25 ± 0.725	6.960 ± 3.828	1.8262 mL/cm2
B	2.36 ± 0.38	1.000 ± 1.355	1.1346 mL/cm2

In a study conducted by **noopr priya et al**^[3] the incision haemorrhage { in ml} was very less in electrocautery group compared to scalpel group which was 1.000 ± 1.355 and 6.960 ± 3.828 respectively. This study was in concordance with a study conducted by **Talpur et al**^[10] in which he found out that mean incision haemorrhage was 1.1346 mL/cm2 in electrocautery group compared to steel scalpel group, 1.8262 mL/cm2. Both these study results were statistically significant ($p < 0.0001$), and our study is consistent with above studies.

3. Pain score on post operative day 1

In our study comparison between pain in post operative day 1 in study groups A and B was 6.40 ± 0.766 and 2.86 ± 1.074 respectively, results showed very less pain in diathermy group, and was statistically significant ($p < 0.0001$).

Table 12 Comparison On Post Operative Pain On Day 1 Between Various Study Groups

Group	Present study	Noopur Priya et al	Bhupender Kadyan et al
A	6.40 ± 0.766	6.24 ± 0.94	6.18 ± 0.91
B	2.86 ± 1.074	5.32 ± 0.68	4.93 ± 0.36

In the above studies it can be seen that electrocautery incision is far better in reducing pain on post operative day 1 compared to steel scalpel incisions. A study conducted by **Sangameshwar Annarao Patil et al** on **Electrosurgery versus steel scalpel for elective surgery**^[19] stated that electrosurgery group had a significantly lesser postoperative pain score at 6 h, 12 h, and 24 h. Study conducted by **Bhupender Kadyan et al**^[13] in 2014, he compared post operative pain in appendicectomy as well as cholecystectomy cases, both

findings were suggestive of better pain control in diathermy group compared to scalpel group. In appendicectomy cases mean pain score on day 1 was 6.18 ± 0.91 and 4.93 ± 0.36 in group A and B respectively. In cholecystectomy cases it was found that pain score for group A was 6.84 ± 0.84 and for group B was 4.82 ± 0.44 . Both these studies were statistically significant ($p < 0.0005$ and < 0.0001 respectively).

4. Pain score on post operative day 2

In this present study comparison between pain score in post operative day 2 in study groups A and B was 4.92 ± 0.872 and 1.12 ± 0.673 respectively. Pain was significantly less in diathermy group compared to steel scalpel group ($p < 0.0001$).

Table 13 Comparison Of Pain Score On Post Operative Day 2 Between Various Study Groups

Group	Present study	Talpur et al	Bhupender Kadyan et al
A	4.92 ± 0.872	2.1049	4.29 ± 1.18
B	1.12 ± 0.673	1.6206	2.580 ± 0.38

In above studies it can be seen that mean pain score on post operative day 2 was significantly less in group B, and our study is consistent with above studies. A study conducted by **omobolaji et al**^[9] in 2015 concluded that cumulative numerical rating scale score for pain was 12.65 (standard deviation [SD] 8.06) and 17.12 (SD 9.49) in the diathermy and scalpel groups respectively ($P < 0.001$). A study conducted by **Summaya Saeed**^[6] on **Scalpel versus diathermy of midline skin incisions: comparison of mean pain score on second post-operative day** showed that the mean post-operative pain scores at 48 hours in diathermy group was 1.48 ± 0.68 while in scalpel group it was 2.17 ± 0.46 ($p < 0.05$), and it was statistically insignificant.

5. Pain Score On Post Operative Day 3

In our study comparison between pain score in post operative day 3 in study groups A and B was 3.71 ± 0.843 and 0.62 ± 0.678 respectively. Pain was significantly less in diathermy group compared to steel scalpel group ($p < 0.0001$).

Table 14 Comparison Of Pain Score On Post Operative Day 3 Between Various Study Groups

Group	Present study	Noopur Priya et al	Bhupender Kadyan et al
A	3.71 ± 0.843	4.90 ± 0.89	2.61 ± 0.61
B	0.62 ± 0.678	3.56 ± 0.64	1.12 ± 0.43

In the above studies it can be seen that pain score on post operative day 3 was significantly less in surgical diathermy group compared to steel scalpel group, and is accordance with our study. A study conducted by **L.D. Prakash et al**^[8] showed that there was no significant difference in pain on any of the postoperative days between the two groups. And study done by **Chukwuma okereke et al**^[1] showed that the mean pain score was higher in the diathermy incised wounds, but this was not statistically significant ($P = 0.094$).

6. Wound Examination On Follow Up.

In our study on comparing the two study groups on post operative day 10, according to southampton scoring system, it was found to have normal healing {Score- 0} in 61 patients of group A and 62 patients in group B. There was found to have some bruising {score 1a}, 2 patients in each group. Mild erythema {score 1c} noted 1 patient of both the group. Erythema along with rise in skin temperature noted along the length of the wound {score 2c} in a patient of group A. But all these results were statistically insignificant ($p = 0.779$).

In our study comparison between wound healing between study groups on post operative day 30, revealed, a score of zero { normal healing } according to Southampton grading system. And that was consistent with a study conducted by **V Kumar et al** in 2011, showed that there was no difference between the groups in wound complications and cosmetic results before discharge and at 1-month follow-up.

A study conducted by **omobolaji et al**^[9] in 2015 concluded that there was no statistically significant difference in wound infection and wound closure (epithelialization time) ($P = 0.206$), and was consistent with a study conducted by **Charoenkwan k et al**^[16] in 2012 it was showed that there was no statistically significant difference in overall wound complication rates (RR 0.90, 95% CI 0.68 to 1.18), nor in rates of wound dehiscence (RR 1.04, 95% CI 0.36 to 2.98). A study done by **Altaf amed talpur et al**^[10] in 2015 stated that postoperative wound complications were noticed in 26 (18.18%) patients of group A { steel

scalpel } and 22 (15.71%) patients of group B{surgical diathermy} And that was consistent with a study conducted by **Franchi et al**^[20] in 2001 ,that revealed a higher incidence of severe wound complications in the scalpel group than in the electrocautery group (8 of 531 versus 1 of 433, P<0.05).

CONCLUSION

Based on the results of this study it may be concluded that skin incisions made by surgical diathermy are quicker and associated with less blood loss than those made by scalpel. It is also associated with lesser post operative pain compared to scalpel group. However no difference in wound complication and wound healing noted in between the two groups on follow up. Hence surgical diathermy is a safe technique for elective skin incisions.

Limitations Of The Study

Although the research was carefully prepared, I am still aware of its limitations and shortcomings.

1. Small sample size.
2. Pain was assessed using numerical pain scale, threshold of pain differs between individual patients.
3. Short follow up {abnormal scar formation such as hypertrophic scar/keloid formation not assessed}

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