

**EFFICACY OF DIATHERMY VERSUS COLD SCALPEL SKIN INCISION IN
APPENDICECTOMY: A RANDOMISED CLINICAL TRIAL**

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ABSTRACT

Background: Diathermy is widely used in surgery for tissue dissection except for the skin incision. This is due to the fear of poor scarring, devitalization of tissue and increased chances of wound infection. This study is undertaken to compare the diathermy skin incision over scalpel skin incision in patients undergoing appendicectomy. **Methods:** A prospective double blind randomized clinical trial was carried out in our tertiary centre in BPKIHS, Dharan. In this study 80 patients of acute appendicitis undergoing appendicectomy were divided in Group A (n=40 patients) and Group B (n=40 patients). In Group A skin incision was made with scalpel, and in Group B skin incision was made with diathermy. Incisional time, incisional blood loss, postoperative pain, requirement of additional analgesic dose, wound complications and scar cosmesis were compared between the two groups. The results were finally analyzed using SPSS 16. **Results:** Diathermy significantly reduced the incisional time and incisional blood loss. Significant wound infection was noticed in the skin incision made by cold scalpel. No significant differences in post operative pain and additional requirement of analgesics was noticed in either of the groups. Patient satisfaction and scar cosmesis was superior in the diathermy group. **Conclusion:** The findings of this study recommend the use of diathermy in making skin incision in all the surgical procedures.

KEYWORDS: Diathermy, Scalpel.

INTRODUCTION

The method of making surgical skin incisions with stainless steel blade is an age old method. Surgeons are always eager to search newer methods for making skin incision because those made with scalpel is supposedly associated with more blood loss and pain.^[18] A concern always remains in a surgeon's mind regarding wound complications and inferior cosmetic outcome associated with the use of diathermy for making surgical skin incisions despite evidence from several cohort studies supporting the use of it. Appendicitis being one of the most common surgical emergency worldwide and also common in our institute, no such study comparing the efficacy of scalpel incision versus diathermy incision for appendicectomy had been done separately till date, as per our literature search. Therefore, we conducted this study to determine whether diathermy is a safe and effective means of creating skin incisions in comparison to traditional cold scalpel while doing appendicectomy.

Aims and objectives

To compare the efficacy of diathermy over scalpel skin incision in patient undergoing appendectomy.

Primary end points

To study the

- incision time
- incisional blood loss

Secondary end points

To study the

- postoperative incision site pain and analgesic requirement
- postoperative wound infection
- scar cosmesis
- patient satisfaction.

METHODOLOGY

Study involved all patients who presented to Department of Surgery BPKIHS with the diagnosis of acute appendicitis and underwent appendicectomy. Patient and

assessor were kept blind and the study performed was a prospective 2 arm parallel design Randomized Clinical Trial. Patients meeting the criteria for acute appendicitis were enrolled consecutively from Department of Surgery dated from September 2015 to 31st August 2016 after informed written consent was obtained. Sample size was calculated based on the incisional blood loss in diathermy (0.99ml) and cold scalpel (1.7ml) with the blood loss difference of 0.76 ml and pooled Standard Deviation 0.98ml. 35 patients were needed to detect the significant difference at power 90%, 2sided and $p < 0.05$. However 40 patients were enrolled in each group anticipating that 10 % would be lost to follow up.^[16] All cases diagnosed as acute appendicitis between the age group of 18 to 65 years undergoing appendicectomy were included in this study whereas appendicular abscess, appendicular perforation, gangrenous appendicitis, patient on steroid therapy, anticancer therapy, with Diabetes mellitus, having coagulopathies and those who refused to give consent were excluded from the study. The study protocol was performed in accordance with the principle of the declaration of Helsinki and after being approved by the Institutional Review Committee and Protocol committee of BPKIHS.

Patients were randomized into 2 arms, employing a computer generated table of numbers. A big brown envelope was made and numbered to achieve concealment of randomization recruitment. A subject enrollment form was filled and eligible patient was offered detailed printed information about the proposed study. Patients who agreed to take part in the study were requested to sign the consent form. After the consent was signed, sealed numbered envelopes were opened and patients were recruited to either scalpel group or diathermy group.

Patients with the final diagnosis of acute appendicitis and those meeting the inclusion criteria were included in this study. A prior informed written and understood consent was taken from each patient after explaining in detail about the modes of incision, operative procedures, possible complications and outcomes (incision time, blood loss, wound infection, scar etc). A detailed clinical history, thorough general and physical examinations were carried out and the findings were recorded in the predesigned proforma. Relevant investigations like Complete blood count, Random blood sugar, Sodium, Potassium, Chest X-ray, ECG, Urea, Creatinine, PT/INR, Serology (HIV, Hepatitis B, Hepatitis C), Ultrasonography of abdomen and pelvis were done as and when required. The findings were recorded in the predesigned proforma along with the instruments used, either diathermy or scalpel. After having completed the aforementioned work-up, patients were enrolled in either of the group as per the randomization and allocation concealment.

RESULTS

In Group A – The skin incision was made with scalpel. A scalpel incision was defined as an incision made through skin, subcutaneous tissue and superficial fascia with a scalpel.

In Group B- The skin incision was made with diathermy needle using pulse sine wave current in —cutl mode and power setting of 70 watts (SPARK -225). A diathermy incision was defined as an incision made through skin, subcutaneous tissue and superficial fascia.

Hemostasis was secured by forceps coagulation using pulse sine wave on power supply of 30 watts in both the groups.

Surgery was performed either on spinal anesthesia or general anesthesia as per the decision of the anesthesiologist. Standard operative procedure was performed by a qualified surgeon.

The skin incision was carried through subcutaneous tissue using either diathermy or scalpel until the external oblique aponeurosis (fascia) was exposed. The incisional time and incisional blood loss were noted and were recorded in predesigned proforma.

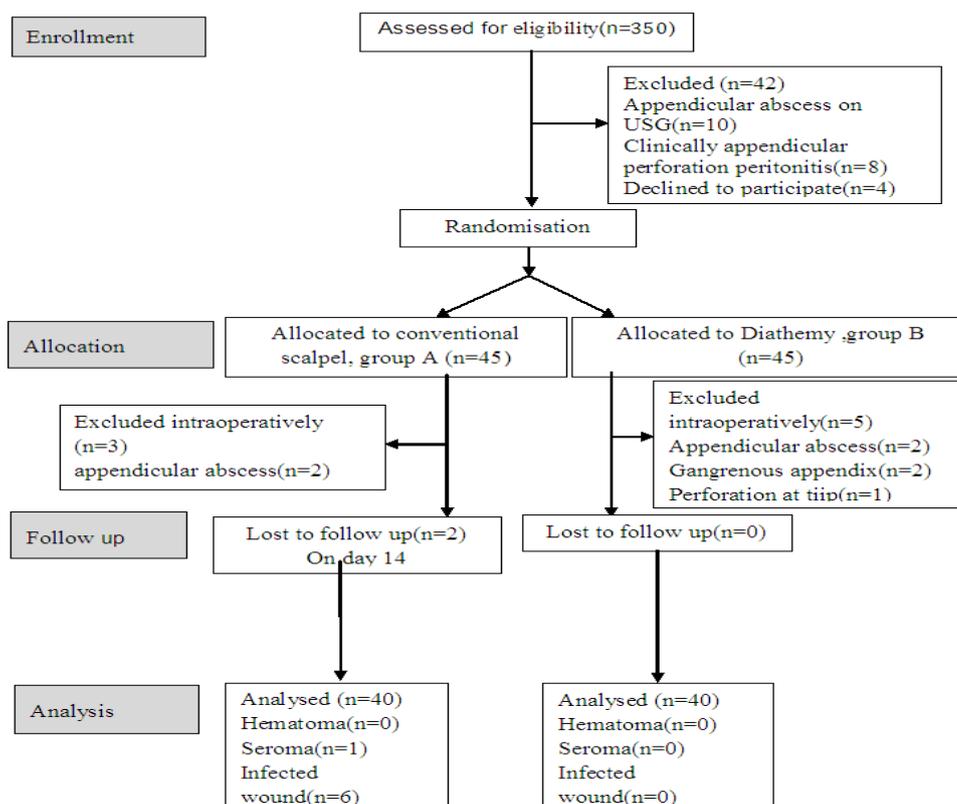


Fig: CONSORT flow chart of our study.

Baseline Characteristics

| Baseline characteristics | Diathermy | Scalpel |
|-----------------------------------|----------------------------|------------------------|
| 1. Age (mean±SD) | 30.2±11.94 | 30.30±13.26 |
| 2. Sex | M=27(67.5%) F=13(32.5%) | 23(57.5%) 17(42.5%) |
| 3. Total leucocyte count (median) | 10.800/mm ³ | 11750/mm ³ |
| 4. USG failure rate (over all) | -----8.8%----- | |

Primary outcomes

| Primary outcomes | Diathermy | Scalpel | Test (T-test) |
|-----------------------------|-----------|---------|---------------|
| 1. Incisional time (median) | 34.5s | 93s | p<0.00 |
| 2. Blood loss (mean) | 0.37ml | 1.36ml | p<0.00 |

Secondary outcomes

| Secondary outcomes | Diathermy | Scalpel | Test result |
|-------------------------------------------------|-----------------------------------------|----------|-------------|
| 1. Postoperative pain | -----statistically not significant----- | | |
| 2. Additional analgesics requirement (mean ±sd) | 1.28±0.75 | 1.38±0.5 | p<0.568 |
| 3. Local wound complication | 15% | 0% | p<0.01 |
| 4. Patient satisfaction | 85% | 67.5% | p<0.001 |

Age distribution

The age of patients enrolled in this study ranged from 18 years to 65 years. The mean age in diathermy group was 30.2 yrs and 30.3 yrs in the scalpel group.

were female where as in Diathermy group among 40 patients, 27(67.5%) were male and 13(32.5%) were female.

Sex Distribution

In our study, among 80 patients, 50(62.5%) were male, 30(37.5%) were female, (M:F = 5:3). In Scalpel group among 40 patients, 23(57.5%) were male and 17(42.5%)

Incisional time

Incisional time was the time taken to make skin incision and achieve hemostasis. It was assessed using a digital stop watch. In our study, in the scalpel group, incisional time ranged from 8s to 208s with an average of 93s,

whereas in diathermy the incisional time was ranged from 10s to 160s with an average of 34.50s. This result was statistically significant between the two groups ($p < 0.000$).

Incisional blood loss

Preoperatively weight of the swab was taken. The number of swabs used during the time of incision until hemostasis was achieved in both types of skin incisions was weighed using digital weighing machine. The blood loss was calculated by subtracting the weight of swabs preoperatively from the weight of the swabs after mopping. In our study, incisional blood loss in the scalpel group ranged from 0.00ml to 3ml with an average of 1.36ml, whereas the range of blood loss in the diathermy group was from 0.00ml to 3.46ml with an average of 0.37ml, which was statistically significant between the two groups ($p < 0.000$).

Post operative pain and analgesics requirement

The post-operative pain was evaluated by a Visual Analogue Scale within 6hrs, 12hrs, 24hrs and 48 hrs and day 3 of surgery. They were questioned about the severity of pain by using Visual Analogue Scale. The pain score of 1-2 was regarded as mild pain, 3-5 as moderate pain, 6-8 as severe pain and 9-10 as worst pain. The results analyzed by Mann-Whitney test revealed no significant difference between the two groups.

In our study, pain score was comparable in the respective periods in both the groups. However at 12 hours post surgery, pain score was more in scalpel group. This was, however, statistically insignificant.

Post operative wound complications

Wound classified as G3 (clear or serosanguinous discharge) or G4 (purulent discharge) was considered as infected and it was confirmed by the presence of pathogenic organism in wound swab culture and sensitivity.

In our study 15% of the wounds got infected in the scalpel group whereas no wound infection was detected in the diathermy group. Thus, this comparison showed significant difference between the two groups [$p < 0.011$] at C.I. 95%]

a. Hematoma

Hematoma was defined as the collection of blood clots.

This was recorded as a binary variable (Y/N) at different time intervals (day3, 14).

In our study, there was no case of hematoma formation in either of the groups.

b. Seroma

Seroma was defined as collection of serous discharge in suture site.

This was recorded as a binary variable (Y/N) at different time intervals (day3, 14). There was a single case of seroma reported in scalpel group on day 3 post-operatively. However no seroma was noted in either of the groups on Day 14.

Scar cosmesis

Aesthetic appearance of wound was assessed on day 28 using a VLA score of 0-10, where 10 indicated an excellent outcome and 0 indicated poor aesthetic outcome. In our study, the average patient assessment scar score in the scalpel group was found to be 13.85 ± 4.938 and 12.33 ± 3.710 in the diathermy group. However, this was of no statistical significance.

| Patient Scar Assessment Scale (PSAS) | | | | | | | | | | | | |
|---------------------------------------------------|--------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | No, no complaints | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Yes, worst imaginable |
| Is the scar painful? | | <input type="radio"/> | |
| Is the scar itching? | | <input type="radio"/> | |
| | No, as normal skin | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Yes, very different |
| Is the color of the scar different? | | <input type="radio"/> | |
| Is the scar more stiff? | | <input type="radio"/> | |
| Is the thickness of the scar different? | | <input type="radio"/> | |
| Is the scar irregular? | | <input type="radio"/> | |
| Overall patient scar satisfaction | | - | - | - | - | - | - | - | - | - | - | + |
| PSAS total score: _____ (minimum, 6; maximum, 60) | | | | | | | | | | | | |

Patient satisfaction

Patient assessment for satisfaction was assessed on day 28 by using a 5 point assessment scale. It was assessed using alternative bipolar scale-Visual mode and Aural mode.

Visual mode: Patient who came on follow up on day 28 were provided with alternative bipolar scale printed in

Nepali language and asked to choose the available options in the paper.

Aural mode: Patient who didn't come on follow up on day 28 were telephoned and asked for the level of satisfaction provided in the alternative bipolar scale.

Alternative Bipolar Scale - Visual mode
 Overall, how satisfied were you with _____? Please check only one box.

| | | | | |
|--------------------------|--------------------------|------------------------------------|--------------------------|--------------------------|
| Completely Dissatisfied | Somewhat Dissatisfied | Neither Satisfied nor Dissatisfied | Somewhat Satisfied | Completely Satisfied |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Alternative Bipolar Scale - Aural mode
 Overall, how satisfied were you with _____? Would you say that you were completely dissatisfied, somewhat dissatisfied, neither satisfied nor dissatisfied, somewhat satisfied, or completely satisfied? [RECORD ONE ANSWER.]

In scalpel group fourteen patients (35%) were completely satisfied, 13 patients (32.5%) were somewhat satisfied and 13 patients (32.5%) were neither satisfied or nor dissatisfied with the outcome of the treatment. In Diathermy group 18 patients (45%) were completely satisfied, 16 patients (40%) were somewhat satisfied and 6 patients (15%) were neither satisfied or nor dissatisfied with the outcome of the treatment.

Finally, we divided the patients' level of satisfaction into 2 headings i.e. patient with satisfaction and without

satisfaction, and level of significance was evaluated by chi-square test which was statistically significant ($p < 0.001$)

Statistical Analysis

Statistical analysis was performed by using SPSS version 16. The inferential statistics was calculated using Pearson's Chi-square test, Mann Whitney U test, Student T-test. A value of $p < 0.05$ was considered significant.

ILLUSTRATIONS



Fig. 1: weighing machine used in our study



Fig. 2: Incision made by scalpel



Fig. 3: Seroma



Fig. 4: Purulent collection



Fig. 5: Incision made by diathermy.

DISCUSSION

Surgeons have always been in search of an ideal method for making skin incision which would provide quick and adequate exposure with minimum incisional blood loss. In the earlier days when explosive anesthetic agents were in use, electrosurgical instruments were not used as extensively because of explosive risks associated with these agents. After the invention of non-explosive anesthetic agents like halothane, electrosurgical instruments like electrocautery were used more frequently for tissue dissections except for skin incisions. This reluctance for use of electrocautery in skin incision was attributed to the belief that these instruments caused devitalization of tissue within the wound which consequently led to wound infection, delayed wound healing and adverse wound scar formation. Back then, electrocautery was mainly used for hemostasis and less often for skin incision.^[18] The fear of tissue injuries was first unfolded when electrocautery was used by Peterson in reconstructive and cosmetic faciomaxillary surgery, Mann and Klippel in paediatric surgery, Kamer in rhinoplasty and Tabin in blepharoplasty with minimum scarring and excellent results. The electrocautery skin incision in general surgery was first reported by Dixon and Watkin in patients undergoing inguinal herniorrhaphy and cholecystectomy.

The role of diathermy, now, is not only limited to general surgical procedures as many clinical trials have compared the usefulness of scalpel and diathermy in making skin incisions in other specialties as well. The aim of this study was to compare the efficacy of the cold scalpel to diathermy skin incisions in appendicectomy with respect to incisional time, incisional blood loss, post operative pain, additional requirement of analgesics, post operative wound complications and scar cosmesis. Only one operation was selected for the study to remove the confounding variables in terms of different operations.

In a study done by Kearns *et al*, laparotomy incisions using electrocautery were significantly quicker than scalpel skin incisions (mean 6.1 ± 0.4 vs. 7.5 ± 0.5 s/cm²; $p < 0.04$).^[13] Similarly, in a study by Ahmad *et al*, the time taken to complete the incision was significantly less with electrocautery ($p < 0.000$).^[11] Likewise, significant difference for incisional time was seen in a study carried

out by Shamim M (mean 6.25 ± 0.51 vs. 9.47 ± 0.84 s/cm²; $p < 0.001$).^[16] There is an equivocal evidence in our study that the mean time taken in the scalpel group was more than that in the diathermy group which is comparable to other studies done in the past, diathermy being quicker.

In a randomized trial done by J.R.C.Telfer, G.Canning and D.J.Galloway *et al* on abdominal incision techniques over a total of 101 patients receiving full-length midline laparotomy for gastrointestinal resections concluded that the electrosurgical method is associated with less blood loss during incision.^[20] However, a study done by Kerans SR and colleagues on 100 patients requiring midline incision in laparotomy, showed no significant blood loss difference between the two groups.^[13] In another study done by Sheikh to evaluate safety and efficacy of Micro-needle Electrocautery Scalpel (MES) versus steel scalpel for skin incision on 177 neurosurgery patients, found significant lesser blood loss in MES group.^[17] There is an equivocal evidence that the incisional blood loss in scalpel incision is more compared to diathermy in studies done in the past which is supported by our study as well.

In a study by Hussain, the mean pain score for diathermy, measured by visual analogue pain score, was 4.35 ± 2.02 and for scalpel was 6.75 ± 2.29 . There was no significant difference at 18 hrs post surgery ($p > 0.05$) between the two groups.⁹ In a study by Shivagouda P *et al*, the p value at 6 hours post surgery was ($p = 0.475$), at 12 hours post surgery was ($p = 0.556$) and at 24 hours post surgery was ($p = 0.762$).^[18] The results of other studies are comparable to ours and there is no significant difference regarding the quantum of postoperative pain.

A comparative study was done by S.A. Hussain and S. Hussain in the year 1988 over a total of 200 patients undergoing cholecystectomy for skin incision with knife or diathermy and their effect on postoperative pain. Results of the Visual Analogue Pain Scale showed a wide range of values at different time period. Significantly smaller pain scores were reported in patients with diathermy incision. Here the patient demanded fewer morphine injections and required less analgesia than those with scalpel incision. In conclusion, cutting diathermy may be superior to the scalpel in making incision less painful.^[9] Kerans SR and colleagues

studied 100 patients requiring midline incision in laparotomy. The results showed lesser pain score and requiring lesser dose and duration of analgesic in diathermy group as compared to scalpel skin incision.^[13] A prospective randomized control trial in the year 2010, by Patil Shivagouda, B.V. Gogeri compared the efficacy of diathermy skin incision versus scalpel skin incision in patients undergoing inguinal hernia repair. The two groups did not differ in relation to post operative pain. Post operative analgesic requirement were similar in two groups.^[18] On contrary to the previous studies, the finding in our study is different as the two groups do not differ in relation to requirement of additional analgesics for post operative pain.

In a randomized study carried out in 1990 by C.D. Johnson and J.W. Serpell among 240 patients undergoing exploratory laparotomy, the result showed both infection and inflammation were equally frequent in both the cases.^[12] In a similar study by Ali Siddhique et al, Superficial SSI was noted in 12.5% cases with electrocautery and 17.5% cases with scalpel, which was statistically insignificant (p value =0.378).^[2] A prospective and randomized, blinded clinical trial conducted by Gary Groot and Chappell over 492 patients over a period of 15 months, to determine whether electrocautery as a means of creating abdominal or thoracic wounds would result in increased wound infection rates, accomplished that the use of electrocautery to create surgical wounds does not increase wound infection rates.^[8] A study by Ali Q and colleagues comparing Superficial Surgical Site Infection (SSSI) in diathermy and scalpel skin incision in inguinal hernioplasty, showed that SSSI was noted in 12.5% cases in Group 1(electrocautery) whereas in Group 2(scalpel) it was 17.5% but this difference was not found to be statistically significant (p value-0.378) and concluded that use of diathermy for making skin incisions is as safe as scalpel and there is no significant difference between them regarding wound infection.^[2] Contrary to all these studies, in our study infection rate is high in scalpel group than in diathermy group.

Prospective randomized study done by Chowdri NA and colleagues compared electrocautery and scalpel. The study showed that electrocautery skin incision resulted in cosmetically better scars compared to scalpel.^[5] In a study on Comparison of Cosmetic and Patient Satisfaction Outcomes of Different Incision Methods, no difference in cosmesis or patient satisfaction was noted.^[10] In a Randomized double-blind trial comparing the cosmetic outcome of cutting diathermy Versus scalpel for skin incisions, cutting diathermy was found to be more cosmetically acceptable in abdominal skin incisions.^[3] Contrary to the studies done in the past, we have come to a conclusion that despite comparable results with respect to scar assessment in both the groups, the overall patient satisfaction is found to be significantly higher in the diathermy group.

CONCLUSION

Diathermy significantly reduced the incisional time and incisional blood loss. Significant wound infection was noticed in the incision made by cold scalpel. No significant differences in post operative pain and additional requirement of analgesics was noted while comparing the two groups. Patient satisfaction and scar cosmesis was superior in diathermy group. The findings of this study recommends the use of diathermy in making skin incision in all the surgical procedures.

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