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Original Research Article

Comparative randomized controlled clinical trial of diathermy versus scalpel incision in midline laparotomy

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ABSTRACT

Background: Laparotomy incisions have traditionally been made using a scalpel. Diathermy, a latest technique, is thought to increase the risk of infection, impair healing and decrease cosmesis. Recent studies suggest that diathermy may offer likely advantages with respect to blood loss, incision time and postoperative pain. The aim of this study was to compare the efficacy and safety of surgical diathermy incisions versus conventional scalpel incisions for midline laparotomy in our hospital with an aim to evaluate diathermy as an operational alternative to scalpel incision.
Methods: This was a prospective randomized clinical study which was conducted in the surgical wards of Medical College & SSG hospital, Vadodara, between December 2013 and December 2014. Patients were randomly assigned to two groups i.e. Group A (scalpel group) and Group B (diathermy group).
Results: A total of 148 patients were enrolled in the study. Of these, 74 patients were randomized to Group A (scalpel group) and 74 patients to Group B (diathermy group). The two groups did not vary significantly in relation to age and sex (p>0.001). Laparotomy skin incisions using diathermy were significantly quicker than scalpel incisions (p=0.624). There was significantly less blood loss in the diathermy group compared with the scalpel group (P=0.15). The mean visual analogue scale was significantly reduced more in the diathermy group than in scalpel group patients on postoperative day 1 (p=0.81), day 3 (p=0.71) and day 5 (p=0.79) respectively. Postoperative complication rates did not differ significantly between the scalpel and diathermy groups (p=0.624).
Conclusions: We concluded that diathermy incision in midline laparotomy has significant advantages compared with the scalpel because of reduced incision time, less blood loss, reduced early postoperative pain and postoperative wound infection.

Keywords: Diathermy, Incision, Mid line laparotomy, Scalpel

INTRODUCTION

Laparotomy skin incisions are made by scalpels with disposable knives, these incisions are associated with more blood loss and pain.[1] Surgical diathermy was introduced at the beginning of the 20th century to preclude the integral drawbacks of steel scalpel.[2-4] It is well thought out to be competent mode of dissection being hemostatic and suitable.[4-6] With the introduction of recent electrosurgical units accomplished of distributing pure sinusoidal current, this technique is now exceptionally popular because of rapid haemostasis, faster dissection and reduced overall operative blood loss.[7-9]

In diathermy, a potential gradient dependent current is passed through the tissue at high frequency (greater than 100000Hz) to excite tissue molecules such as water resulting in precise tissue lyses, which can be used for employed to coagulate (modulated mode) or to cut (sinusoidal mode) the tissue. This principle permits the use of diathermy electrode without causing adjacent

tissue injury.[4,10] Diathermy incision is not a true cutting incision.[9-11] This method heats cell within tissues so rapidly that they vaporize, leaving cavity within cell matrix, heat generated evaporates as steam, rather than being transferred to adjacent tissues. As electrode is moved forward new cells are contacted and vaporized with creation of incision. This clarifies absence of scaring and successive healing with less scarring.[9,11]

Despite these results and benefits, the indication of using diathermy as a 'cutting' tool for skin and surgical incisions has been precluded by many surgeons for the alarm of delay wound healing and the risk of infection and this have reduced the widespread use of surgical diathermy for skin incisions.[4,9,11] Midline laparotomy delivers rapid, easy and extensive access to almost all the structures of abdomen and retroperitoneum. Yet, it is related with significant morbidity when compared to other abdominal incisions.[4,11] The suitable surgical technique has been a major apprehension among surgeons as it has been shown to affect healing following midline laparotomy.[4,12] Conversely, diathermy has been described to be used in midline laparotomy incisions as internationally carried out studies have shown it to have significant benefit over traditional scalpel incision based on incision related blood loss, post-operative pain. Moreover, they also show that there was no difference between the two in terms of postoperative wound complications.[13]

Many randomized clinical trials have been conducted to compare diathermy incision with scalpel incision over skin in midline laparotomy and many of them showed diathermy incision is better than scalpel incision in terms of time taken for incision, lesser pain, better wound healing and little blood loss.[4,9,13,14] However, despite this evidence in many randomized clinical trials in support of diathermy use in skin incision, many surgeons in many hospitals including ours are unwilling in using diathermy for making skin incisions.[9,11] This prospective randomized clinical trial was conducted at authors' hospital to compare the efficacy and safety of surgical diathermy incisions versus conventional scalpel incisions for midline laparotomy in authors' local setting with an aim to evaluate diathermy as an effective alternative to scalpel incision.

METHODS

This study was a prospective randomized clinical study which was conducted in the surgical wards of SSG hospital between December 2013 and December 2014. The inclusion Criteria were all patients more than 18 years undergoing midline laparotomy during the period can take part under study. The patients who had previous midline laparotomy, on concurrent anticoagulant or corticosteroid therapy, had diabetes mellitus and were less than 18 years of age are excluded. All patients who met the inclusion criteria were, after informed written consent, consecutively enrolled in the study. The patients included in the study were randomized into two groups according to whether the diathermy or scalpel was used in making skin incision. A computer program (random number generator, Microsoft excel 5.0) was used to generate random number list, whereby patients were assigned to either of the two groups i.e. Group A consisting of patients receiving scalpel skin incision (scalpel group) and Group B consisting of patients receiving diathermy skin incision (diathermy group). These two groups were divided in subgroup as Elective Laparotomy and Emergency Laparotomy.

- Group A-Elective: Patients receiving scalpel skin incision (scalpel group) in elective midline laparotomy.
- Group A-Emergency: Patients receiving scalpel skin incision (scalpel group) in emergency midline laparotomy.
- Group B-Elective: Patients receiving scalpel skin incision (diathermy group) in elective midline laparotomy.
- Group B-Emergency: Patients receiving scalpel skin incision (diathermy group) in emergency midline laparotomy.

In the group of patients receiving scalpel incision (Group A), scalpel with disposable blade was used to incise skin till peritoneum whereas in Group B incision was made through skin and deeper tissues with diathermy using diathermy pen electrode, Alan electrocautery brand ELSY 360 M by Alan electrocautery system private limited, set at pure cutting mode and delivering 417kHz sinusoidal current, was employed to incise skin and all the layers.

Figure 1: Electrocautery pencil.

Figure 2: Electrocautery machine.

Figure 3: Scalpel.

In both group's diathermy was used in coagulation mode for hemostasis. The surgeon was informed of the type of skin incision to be used just before the start of the skin incision.

Study variables analysis

Incision time: The length and depth of incision at the end of the procedure was measured in centimeters using a sterile flexible rule. Incision area was calculated as the product of the length and depth of skin incision. Incision time (from the initial skin incision till complete opening of peritoneal cavity, including hemostasis), calculated in seconds per unit wound area (sec/cm^2), was also noted.

Incisional blood loss: Blood loss during skin incision was calculated by weighing the swabs used exclusively in making the incision and during haemostasis with each gram taken as equal to one milliliter of blood (i.e. 1g=1ml). No suction evacuation of blood was done while making the skin incision. The amount of blood will be calculated as ml/cm^2.

Post-operative pain: Postoperative pain assessed according to a visual analogue scale (VAS) from 0 (no pain) to 10 (worst pain imaginable) on 1st, 3rd, 5th, 7th and 10th post-operative day.

Postoperative wound infection: Wound assessed clinically for wound infection 1st, 3rd, 5th, 7th post-operative day and day of discharge.

Statistical analysis

Descriptive statistics applied to calculate mean and standard deviation for age, and frequency for gender. The amount of wound related blood loss, incision time and the severity of wound related pain in both groups compared using student t-test, while post-operative wound infection in two groups compared using Fisher's exact test. The amount of wound related blood loss, incision time and the severity of wound related pain, post-operative wound infection compared in elective midline laparotomy groups and emergency midline laparotomy groups differently.

Sample size and study population

By taking incisional time as significant parameter and by taking alpha error 5% and power (1-beta) and clinically significant mean difference in time 0.5sec/cm^2 required sample size in each group was 63. This calculation was done by using nMaster1.0 software.

RESULTS

One forty-eight patients who underwent midline laparotomy were randomized prospectively to either diathermy group or scalpel group for skin incision. There was no significant demographic, age as well as sex difference between two groups noted incision time was measured as mean incision time (seconds) per incision area (cm^2). In present study results were analysed with T-test. There was no significant difference between two groups.

Results were also compared separately for emergency and elective patients. There was no significant difference between two groups in emergency as well as elective patients but incision time was overall less in diathermy group in emergency as well as elective patients.

Incision blood loss was measured as mean incision blood loss (ml) per incision area (cm^2). In present study results in Table 1 were analysed with T-test. There is no significant difference between two groups. Results were also compared separately for emergency and elective Patients. There was no significant difference between two groups in emergency as well as elective patients but incisional blood loss was overall less in diathermy group in emergency as well as elective patients.

Incisional blood loss was ranging from 8 to 27ml in both groups. Post-operative pain was assessed by visual analogue scale at 1, 3, 5,7,10 days after surgery. In present study results are analysed with T Test. There was no significant difference between two groups. Results were also compared separately for emergency and elective patients. There was no significant difference between two groups in emergency as well as elective patients. But Post-operative pain scores on day 1,3,5,7 & 10 were overall less in diathermy Group in emergency as well as elective patients.

Post-operative wound infection was assessed by presence of redness, pus discharge, or seroma at 1, 3, 5, 7, 10days after surgery. In present study results are analysed with Fischer's exact test. There is no significant difference between two groups. Results were also compared separately for emergency and elective patients. There was no significant difference between two groups in emergency as well as elective patients but incidence of post-operative wound infection was overall less in diathermy group in emergency as well as elective patients.

Table 1: Age distribution of patients.

Patient characteristics	Group A	Group B	P Value
Number of patients	74	74	-
Mean age (in years)	40.2±17.3.	39.9±15.36	-
Sex ratio (male:female)	2.7:1	3.1:1	-
Mean incision time (sec/cm^2)	6.83±0.48	6.77±0.55	P=0.482
The mean incision blood loss (ml/cm^2)	1.62±0.088	1.60±0.082	P=0.15
Mean Visual Analogue Score (VAS)			
Day 1	5.12±0.34	5±0.63	0.53
Day 3	4.09±0.27	3.93±0.54	0.31
Day 5	3.09±0.27	2.96±0.49	0.37
Postoperative wound infection rate (%)	11 (14.8%)	8 (10.8%)	P=0.624

DISCUSSION

Since it was first familiarized at the beginning of the 20th century, surgical diathermy has more and more been used for tissue dissection, being hemostatic and convenient.[2-4,6]. The surgeons, conversely, continue to be hesitant when it comes to the use of diathermy for making an incision of skin and fascia.[4,9,11] This hesitancy, which stems partly from previous studies that the use of diathermy causes devitalization of tissue within the wound which subsequently lead to wound infection, delayed wound healing and excessive scarring has been earnestly confronted by recent randomized clinical trials, which suggests diathermy to be safe option with absolute advantages and no added risk profile.[4,9,13,14] Despite this evidence in these randomized clinical trials in support of diathermy use in making skin incisions, many surgeons in many hospitals including our hospital still advocate the use of scalpel in making skin incisions.[9,11] So, this study was aimed at investigating this alternative method of incision with comparison to the scalpel incision with regards to advantages, like time and bleeding, as well as alleged complications i.e. postoperative pain and wound infection.

Studies conducted in humans provided conflicting results. Soballe et al, reported that electric coagulation increases the incidence of indurated margins, infections, and weakness of the wound cut in comparison with the knife.[15] Conversely, Groot et al, reported that use of surgical diathermy to create surgical wounds in patients undergoing abdominal or thoracic operations carries a wound infection rate similar to that of scalpel.[16]

Several randomized clinical studies have been conducted to compare diathermy incision with scalpel incision over skin and many of them showed diathermy incision is better than scalpel incision in terms of time taken for incision, lesser pain, better wound healing and little blood loss.[1,6,9,12,13,17-19] In agreement with other studies, the present study has shown that diathermy incision in elective midline laparotomy has significant advantages compared with the scalpel because of reduced incision time, less blood loss, reduced early postoperative pain.[1,4,13] In addition, our study showed no significant difference between the two groups in post-operative wound infection.

The fear of tissue injury in diathermy incision was first unfolded when this technique was used by Peterson in reconstructive and cosmetic faciomaxillary surgery, Mann and Klippel in paediatric surgery, Kamer in rhytidoplasty, Tobin in blepharoplasty, with minimum scarring and excellent results.[21-23] Kearns et al, who compared electrosurgical and scalpel methods in hundred patients undergoing elective midline incision have indicated that the diathermy incision has significant advantages over scalpel incision based on incision time, blood loss, early postoperative pain and analgesia requirements.[13] Their study found that diathermy was associated with significantly lesser incision related blood loss and was quicker.

Similarly, there was no significant difference in terms of wound complications, including wound infection, as reported by the present study.

The results of this study are also in agreement with that of Telfer et al, which compared 101 patients undergoing midline laparotomy, by either diathermy or scalpel, for intestinal resection.[24]

Diathermy was associated with significantly less blood loss and an insignificant difference in postoperative pain. Contrary to present study, however, their study showed that there was no advantage with diathermy in relation to the incision related time. In keeping with other randomized clinical trials.[4,9,13,14]

Present study showed no advantages of scalpel incision over diathermy incision in midline laparotomy diathermy and can be used as an effective alternative to scalpel incision. Based on this study, it is suggested that in elective midline laparotomy the skin may be safely incised using diathermy as this has shown to be associated with short incision time, less blood loss,

reduced postoperative pain and analgesic requirements in the postoperative period.

CONCLUSION

The study has demonstrated that surgical diathermy is a safe and effective method to make skin incision in elective midline laparotomy and has significant advantages over scalpel skin incision in that it is associated with short incision time, less blood loss, reduced postoperative pain and less incidence of postoperative wound infection.

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