



RANDOMIZED DOUBLE-BLIND TRIAL COMPARING THE COSMETIC OUTCOME OF CUTTING DIATHERMY VERSUS SCALPEL FOR INGUINAL HERNIOPLASTY SKIN INCISIONS.

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ABSTRACT

Background : Skin incisions have been traditionally been used for making skin incisions. Recent studies have shown that cutting diathermy causes less post-operative pain without significant difference in cosmetic outcome or complication rate.

Aim : The aim of this study was to compare the cosmetic outcome of the skin incisions created with cutting diathermy and scalpel by assessing Patient and Observer Scar Assessment scale (POSAS) and Vancouver Scar Scale (VSS) and also comparing post-operative complications between two treatment groups with respect to seroma formation, incisional pain and wound infection.

Methods : This was a prospective hospital based single centre study which was conducted in Dr. Jeyasekharan Hospital and Nursing home from period July 2015 to January 2017. A total of 66 patients who were 18 years and above and diagnosed with inguinal hernia were enrolled in the study. Patients were then randomized for skin incision using either diathermy or scalpel using table of random numbers into two groups of 33 each: Group A (Scalpel group) and Group B (Cautery Group).

Results :

1. Mean age of the study subjects was 50.1 and 45.9 years while mean BMI was 25.8 and 25.3 Kg/m² in scalpel and cautery group respectively (p-0.134 and 0.313).
2. Out of the total 66 subjects, history of smoking was given by 30.3% subjects with no difference between the groups (p-0.789).
3. Out of the total 66 subjects, history of DM was found in 24.2% subjects with no difference between the groups (p-0.775).
4. Out of the total 66 subjects, history of Hypertension was given by 22.7% subjects with no difference between the groups (p- 1.0).
5. Out of the total 66 subjects, no subject has received pre-op chemotherapy.
6. Seroma formation was seen in 6 (18.2%) subjects of scalpel group as compared to 7 (21.2%) subjects in cautery group (p- 1.0).
7. Mean VAS score was seen to be significantly less in cautery group as compared to scalpel group at each follow up (p<0.01).
8. Both the groups were comparable with respect to Vancouver scar scale (10.21 vs 10.76; p-0.051).
9. Both the groups were comparable with respect to objective and subjective component of Patient and Observer Scar Assessment Scale (p-0.11 and p-0.07).
10. Surgical site Infection was seen in 3 (9.1%) subjects of scalpel group as compared to 5 (15.2%) subjects in cautery group (p-0.078).

Conclusion: The present study thus concluded that cautery causes significantly lesser pain without any significant difference in cosmetic outcome or patient's satisfaction. Complication rate was also comparable between the two methods. We, thus recommend universal use of cautery to make abdominal skin incisions for hernia repair.

KEYWORDS :

INTRODUCTION

Incision is a cut or a slit to gain access to the underlying structures. Very few operations can be performed without cutting through the skin. An incision may be used to gain access to deeper structures or surgery may be performed on the skin itself, whether for repair of trauma or for excision of a skin lesion. Surgeons have been in search for ideal methods of skin incisions which would provide quick and adequate exposure with minimal blood loss [1].

Traditionally incisions are made with stainless steel scalpel. These incisions are supposed to be more bloody and painful. To overcome this problem many advanced techniques have come viz laser, plasma scalpel, cavitron surgical aspirator but the above said methods are costly and relatively unavailable at peripheries. However, common practice by most surgeons is still to make skin incisions with a scalpel and to divide the deeper tissues with coagulation diathermy. Electrocautery which is available in all surgical theatres is less frequently used for skin incisions for the fear of tissue damage, post-operative pain, increase in infection rate and scarring. Nevertheless, electrocautery (Diathermy) is frequently used by some surgeons for skin incisions. Various studies [2-8] have been undertaken to evaluate the efficacy of electrocautery over scalpel in making skin incision and the results are varying; some showing better results with electrocautery while some showing similar results.

Skin incisions with electrocautery are not frequent because of the hypothesis that (a) the application of extreme heat may result in significant postoperative pain and poor wound healing because of excessive tissue damage and scarring respectively and (b) skin incision with the use of electrocautery entails increases the risk of wound infection in the presence of an underlying prosthetic material [9]. These presumptions stem from experimental and clinical studies that yielded varied reports [10-12].

Modern electrosurgical units capable of delivering pure sinusoidal currents have evolved a change in this concept. The advantages are rapid hemostasis, faster dissection, and a reduced overall operative blood loss [7,13].

Studies have been performed illustrating the safety and efficacy of diathermy for dividing subcutaneous, muscle and fascial layers [11,14-18]. However its use for incising the epidermis and dermis remains controversial as concern that diathermy creates thermal burn, resulting in a scar that is cosmetically inferior to that resulting from use of a scalpel [19-32].

We thus conducted a prospective double blind randomized controlled trial among the patients undergoing elective ""Lichtenstein"" tension-free inguinal hernioplasty at our hospital and cosmetic outcome between the two treatment groups was

compared.

MATERIAL AND METHODS

Study Design

Hospital based single centre study

Study Duration

The study was conducted for the time period of 1 and 1/2 years from July 2015 to January 2017.

Source of Data

The study was conducted in the department of surgery, Dr. Jeyasekharan Hospital, Nagercoil after prior informed consent from the patients, undergoing elective inguinal hernioplasty ("Lichtenstein" tension free mesh repair).

Sampling Technique & Sample Size:

It can be justified as follows:

$$n = \frac{(Z_{\alpha} + Z_{1-\beta})^2 * 2\sigma^2}{\Delta^2}$$

$$\Delta^2$$

where:

Z_α: is the constant set by accepted error of 5% (value - 1.96)

Z_{1-β}: is the constant set by convention according to power of the study as 80% (value -0.84)

Δ: is the difference in effect of the 2 interventions (taken as 2 point improvement on numeric pain scale rating)

σ: is the mean standard deviate (SD1 + SD2/2)

(The cumulative numerical rating scale score for pain as seen in a study by Chauhan et al. was 12.65 (SD- 8.0) and 17.12 (SD- 9.1)) [18]

$$n - \frac{(1.96 + 0.84)^2 * 2(8.5)^2}{(2)^2}$$

$$(2)^2$$

n – 33 approx. (for each group)

So, final sample size was 66 subjects undergoing elective inguinal hernioplasty ("Lichtenstein" tension free mesh repair).

Inclusion Criteria

All patients aged >= 18 years undergoing elective inguinal hernioplasty ("Lichtenstein" tension free mesh repair) from July 2015 to January 2017.

Exclusion Criteria

1. Patients with existing scar at the planned surgical incision site.
2. Patient with known predilection for keloid formation.
3. Patient diagnosed to have connective tissue disorder (Ehlers-Danlos, Marfan syndrome, scleroderma).
4. Patient not willing to participate in study.

Study Methodology

A total of 66 patients with age 18 years and above diagnosed to have inguinal hernia during the period of evaluation at Dr. Jeyasekharan Hospital and Nursing Home and undergoing "Lichtenstein" tension free mesh inguinal hernioplasty were taken up for the study. A written informed consent was taken from patients who are willing to participate in the study.

Factors like diabetes, age, smoking habit, obesity, preoperative radiotherapy or chemotherapy which were the known factors influencing risk of surgical site infection were recorded for each patient in the data collection forms. Patients were then randomized for skin incision using either diathermy or scalpel using table of random numbers into two groups of 33 each:

Group A: Scalpel Group

Group B: Cautery Group

All patients received standard prophylactic antibiotics 30 minutes prior to incision. The subcutaneous and fascial layers in both treatment groups were divided using diathermy. All patient

underwent "Lichtenstein" tension free mesh repair. Skin was closed using staples in both treatment groups.

Post operatively patients were assessed for incision site pain and requirement of standard analgesics for both the groups. Wound characteristics were recorded at the time of discharge (3rd day). Clip removal on 7th post-operative day and wound was inspected for seroma, infection and other complications. Scar cosmeses at 6 months was evaluated by calling patients at our hospital using Vancouver Scar Scale (VSS) (table 1) and the Patient and Observer Scar Assessment Scale (POSAS) (table 2,3).

TABLE:3 VANCOUVER SCAR SCALE

Pigmentation	Normal 0	Hypopigmentation 1	Hyperpigmentation 2		Score	
Vascularity	Normal 0	Pink 1	Red 2	Purple 3		
Pliability	Normal 0	Supple 1	Yielding 2	Firm 3	Banding 4	Contracture 5
Height (mm)	Flat 0	< 2mm 1	2-5mm 2	>5mm 3		
Total						

TABLE:4 PATIENT AND OBSERVER SCAR ASSESSMENT SCALE:

Objective Scale (Table 4A) and Subjective Scale (Table 4B)

TABLE:4A POSAS Objective Scale

OBJECTIVE SCALE	1 NORMAL SKIN	2	3	4	5	6	7	8	9	10 WORST SCAR IMAGINABLE	TOTAL
VASCULARITY											
PIGMENTATION											
THICKNESS											
RELIEF											
PLIABILITY											
SURFACE AREA											
	TOTAL										

OVERALL OPINION OF THE SCAR COMPARED WITH NORMAL SKIN: _____ (1-10)

TABLE:4B POSAS Subjective Scale

Subjective Scale	1 Normal Skin	2	3	4	5	6	7	8	9	10 Worst Scar Imaginable	Total
Painful											
Itching											
Colour											
Stiffness											
Thickness											
Irregular											
	TOTAL										

OVERALL OPINION OF THE SCAR COMPARED WITH NORMAL SKIN: _____ (1-10)

INVESTIGATIONS REQUIRED

- CBC
- RBS
- Urine Routine
- Blood Urea, Serum Creatinine

Statistical Methods

Data was statistically described in terms of mean (±SD), frequencies (number of cases) and percentages when appropriate. Data were tested first for normal distribution by Kolmogorov– Smirnov test. Comparison of quantitative variables between the study groups was done using Student t test for independent samples if

normally distributed. Mann–Whitney U test was used for non-normally distributed quantitative data. For comparing categorical data, Chi square test was performed. Exact test was used instead when the expected frequency is less than 5. A 'p' value of <0.05 was considered as statically significant. All statistical calculations were done using computer programs Microsoft Excel version 7 (Microsoft Corporation, NY,USA) and SPSS software version 21.0.

RESULTS:

- Mean age of the study subjects was 50.1 and 45.9 years while mean BMI was 25.8 and 25.3 Kg/m² in scalpel and cautery group respectively (p-0.134 and 0.313).
- Out of the total 66 subjects, history of smoking was given by 30.3% subjects with no difference between the groups (p-0.789).
- Out of the total 66 subjects, history of DM was found in 24.2% subjects with no difference between the groups (p-0.775).
- Out of the total 66 subjects, history of Hypertension was given by 22.7% subjects with no difference between the groups (p-1.0).
- Out of the total 66 subjects, no subject has received pre-op chemotherapy.
- Seroma formation was seen in 6 (18.2%) subjects of scalpel group as compared to 7 (21.2%) subjects in cautery group (p-1.0).
- Mean VAS score was seen to be significantly less in cautery group as compared to scalpel group at each follow up (p<0.01).
- Both the groups were comparable with respect to Vancouver scar scale (10.21 vs 10.76; p-0.051).
- Both the groups were comparable with respect to objective and subjective component of Patient and Observer Scar Assessment Scale (p-0.11 and p-0.07).
- Surgical site Infection was seen in 3 (9.1%) subjects of scalpel group as compared to 5 (15.2%) subjects in cautery group (p-0.078).

Demography

Mean age of the study subjects undergoing hernia repair was 48.0 years with mean age of 50.1 and 45.9 years in scalpel and cautery group respectively. Mean BMI was 25.8 and 25.3 Kg/m² in scalpel and cautery group respectively. Both groups were comparable on the basis of baseline demographic variables.

Discussion:

Electrosurgical unit (ESU) is the most common electrical equipment in the modern operating rooms. Surgeons are very comfortable to see a good ESU in the operation theatre which is a part and parcel of surgeon's armamentarium. William T. Bovie, a biophysicist of Harvard Medical School, has been credited for commercially producing the first ESU capable of cutting and coagulating the human tissues in the 1926 [16]. The ESU uses alternating high-frequency current. Frequency is the number of times an AC current reverses its direction in 1s and this is measured in cycles per second or hertz (Hz). Radiofrequency of 10,000 Hz, can pass through the human body without causing stimulation of the muscle or nerve. An ESU uses radiofrequency of 100,000-10,000,000 Hz to cut, coagulate, and desiccate the tissues.

Surgical cut is made when the voltage between the cutting electrode and the tissue to be cut is sufficiently high to produce electric arcs between them (high frequency AC). Peak voltage approximately 200V is required to produce an arc [33].

Several studies have shown that electrocautery is increasingly being used for making skin incisions, securing hemostasis, dissecting tissue planes and cutting [34]. It facilitates hemostasis, reduces overall intraoperative time and lastly produce a wound that heals similarly as one created by the scalpel [34]. Despite these advantages, its use by surgeons for skin incisions in centres in developing countries including ours is still suboptimal.

We can allude to the paucity of studies involving this group of

patients in this region as the cause along with the old belief that electrocautery causes electric burns when used to make skin incisions, thus increasing the amount of devitalized tissue within the wound. Surgeons, generally avoid diathermy for making skin incisions due to suspected delayed wound healing, infections and excessive scarring [9]. The present hospital based randomized double-blind trial was thus conducted to compare the cosmetic outcome, post-operative incisional pain and wound complications between the skin incisions created with cutting diathermy and scalpel.

Complication Rate

Seroma formation was seen in 6 (18.2%) subjects of scalpel group as compared to 7 (21.2%) subjects in cautery group (p- 1.0). Surgical site Infection was seen in 3 (9.1%) subjects of scalpel group as compared to 5 (15.2%) subjects in cautery group (p-0.078).

In our study wound infection rate compared favourably with previous study [7,14,15]. The conclusion was that it was not statistically significant. Groot and Chappell [11] 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. The overall outcome in this study in terms of early and late wound complications is comparable with other similar studies [13,15-17]. There was no adverse effect noted during the course of our study attributable to the use of electrocautery.

In present study, no difference in complication rate was noted between scalpel and diathermy. This is in accordance with the results observed by various other authors [1,9,21-25,29-31]. Chowdri NA et al. even observed significantly lower wound complications rate with diathermy [20].

Post-op Pain

Mean VAS score was seen to be significantly less in cautery group as compared to scalpel group at each follow up (p<0.01). In accordance with previous studies our results suggested a significantly reduced postoperative pain in the diathermy group [1,2,9,18,20-24,28,29,30-32]. This is due to the thermal effect of diathermy on the sensory nerve fibers with the subsequent disruption of transmission of nerve impulses. Cell vaporization caused by the application of a pure sinusoidal current leads to immediate tissue and nerve necrosis without significantly affecting adjoining structures. Consequently, there is total or partial injury to the cutaneous nerves in the area of the surgical wound with a reduced postoperative pain profile in patients who had diathermy skin incisions [17].

In one study by Kearns and colleagues [9] 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. Chryso et al. [22] in their prospective study comparing diathermy and scalpel incisions in tension free inguinal hernioplasty noted lower VAS 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. [7] 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).

Cosmetic Results

In the present study, we found no difference in the quality of wound

cosmesis between scalpel or diathermy skin incisions. Both the groups were comparable with respect to Vancouver scar scale (10.21 vs 10.76; $p < 0.051$). Similarly, both the groups were also comparable with respect to objective and subjective component of Patient and Observer Scar Assessment Scale ($p < 0.11$ and $p < 0.07$).

In a study by Dixon & Watkin [15], 84 patients undergoing inguinal herniorrhaphy or open cholecystectomy were evaluated. The authors found no difference in the patients' assessment of wound cosmesis, but noted a significant preference for the diathermy incisions when they were assessed by a surgeon or nurse. Chau et al. [26] studied 19 patients undergoing bilateral neck dissections, and randomly assigned each side's skin incision to diathermy or scalpel. They found no difference in cosmesis at 6 months post-operatively. Yamamoto et al. [35] compared cosmetic outcomes after breast surgery using electrocautery versus scalpel and scissors to perform the operation. They found worse cosmetic results in the diathermy group, but only in those patients who also underwent radiotherapy (results were equivalent in those patients who were not irradiated). In a meta-analysis by Arid LN et al. [23] a systematic electronic literature search was performed on MEDLINE and PubMed and the methodological quality of included publications was evaluated.

Six RCTs were identified comparing electrocautery ($n = 606$) and a scalpel ($n = 628$) for skin incisions. No significant difference in wound infection rates or scar cosmesis was identified between the treatment groups. Electrocautery significantly reduced the incision time and postoperative wound pain. A trend toward less incisional blood loss from skin incisions made with electrocautery was noted. Authors concluded that electrocautery is a safe and effective method for performing surgical skin incisions.

Conclusion:

The present study thus concluded that cautery causes significantly lesser pain without any significant difference in cosmetic outcome or patient's satisfaction. Complication rate was also comparable between the two methods. We, thus recommend universal use of cautery to make abdominal skin incisions for hernia repair.

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