Cold knife versus monopolar electrosurgery for abdominal incisions (clinical trial)

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Abstract

Background: Scalpel incisions cause low injury to surrounding tissues. Electrosurgery has been used extensively for hemostasis, but the risk of producing huge scars and poor tissue recovery has kept it from being used in skin incisions for the time being.

Aim: In patients with benign gynaecological disorders receiving abdominal incisions, to evaluate early postoperative and late term wound complications among scalpel and electrosurgery.

Patient and method: Within a 20-month period, a randomised controlled trial (parallel group study with 1:1 randomization) was undertaken at the gynaecology department of Alzhraa University Hospital in Cairo, Egypt.

We included 120 women in the trial after determining their eligibility. 16 of them were disqualified for failing to satisfy the inclusion criteria and refusing to participate. During follow-up, 14 patients were lost because they did not attend their second appointment or did not provide their incision photo to the first author (Shaimaa Ismail). Analysis was done on 90 participants, 45 in each group. Cases randomly assigned at the operation day into two groups. Group A: scalpel used for anterior abdominal wall incision and simple compression or stitch for hemostasis , Group B: electrosurgery used for same incision and hemostasis (CUT and COAG). Primary outcomes: wound incision time/seconds and wound related blood loss/grams). Secondary outcomes: postoperative pain by VAS score, analgesia needed in first 12 hours postoperative in number of doses, wound infection and ugly scar formation at day 40.

Results: the electrosurgery group had a significantly low wound related blood loss (7.39 g ± 5.5 g vs. 24.72 g ± 9.75 g; U = 137; P < 0.001) and lesser incision time (2.16±0.09

min vs. 3.9±1.58 min; U= 303; P < 0.001; Mann-Whitney test) compared to scalpel group. Electrosurgery significantly decrease postoperative pain in both subjective and objective methods. There was no statistical difference found between the groups regard to wound infection (P = 0.3; Fisher exact test).

Conclusion: The proper use of electrosurgery for abdominal wall incision could be a good alternative for scalpel.

We registered our study protocol at www.clinicaltrials.gov . ClinicalTrials.gov Identifier: NCT04236401

Keywords: electrosurgery, scalpel, abdominal incision.

Introduction

The employment of an alternating current via tissue resistance to elevate tissue temperature for vaporization or a combination of desiccation and protein coagulation is known as electrosurgery. [1,2] Since Dr Harvey Cushing first introduced electrosurgery on October 1, 1926, it has been frequently employed in surgical operations. [3] However, it is mostly utilized for hemostasis and dissection. The use of electrosurgery for skin incision was thought to be problematic. [4] There are worries about utilizing electrosurgery in skin incisions because of the possibility of big scars and poor tissue repair [5]

Aim

To compare the initial postoperative and late term wound complication degrees among the scalpel and electrosurgery in patients with benign gynecological disorders undergoing abdominal incisions.

Patients and methods

From November 2019 to June 2021, a randomized controlled trial (parallel group study with 1:1 randomization) was undertaken at Alzhraa University Hospital's gynaecological department.

A total of 90 opaque sealed envelopes comprised 45 pieces of written paper for cold knife and 45 pieces of written paper for electrosurgery, all prepared before recruitment and utilized to conceal allocation.

Ethical Approval

Approval of ethical committee was obtained from quality education assurance unit, Al-Azhar university faculty of medicine, Egypt. Oral informed consent was taken from all cases before participation in this study. The nature and aim of this work were fully discussed to all women who were included in the study.

Sampling method

Consecutive sampling (non-probability sample).

Sample size justificationn

The sample size was obtained using the following formula :

$n = (Z\alpha/2+Z\beta)2 *2*\sigma2 / d2,$

where $Z\alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), $Z\beta$ is the critical value of the Normal distribution at β (e.g. for a power of 80percent, β is 0.2 and the critical value is 0.84), $\sigma2$ is the SD of wound incision time of electrocautery from previous study (Kadyan, et al,2014)(6) SD=5.07 , and d is the difference in incision time between the two groups that we expect to detect, d=(3 minutes).

n= (1.96+0.84)2*2*5.072/32 = 44.78 so we will recruit 45 patients in each group with total sample 90 patients and we considered potential dropouts, so we recruited a total sample of 120 patients.

Participants

At morning of the operation, after confirming inclusion criteria, the patient was informed about the study's objectives, and oral consent was obtained. One envelop is randomly chosen and opened, red by the surgeon on the morning of the surgery.

Setting

Inpatient & Outpatient

Inclusion Criteria

All individuals wanting to participate in the research who are scheduled for elective gynecological abdominal operations for benign illnesses. As per hospital regulation, the subjects were given 2 gm second generation cephalosporin 1 hour before surgery. All of the surgeries were performed by a surgeon who works at Alzhraa University Hospital as a lecturer or assistant professor of obstetrics and gynecology.

Exclusion Criteria

Antibiotic use in the last seven days, chronic medical conditions such as diabetes, asthma, or TB, anemia, surgically scarred tissues, immune-compromised individuals, pregnant women, patients with pacemakers devices, and patients on anticoagulant treatment.

Intervention

scalpel incision (A) or monopolar electrosurgery incision (B)

The abdominal skin and vagina were prepared as local hospital policy with povidone iodine in the operating room. All operation done through lower transverse incision under spinal anesthesia.

Accordingly, group A, scalpel used to incise abdominal wall including skin ,subcutaneous tissue and anterior rectus sheath and hemostasis was achieved by either simple compression of skin blood vessel or stitch while in group B, abdominal wall including same previous layers opened by electrosurgery unit cutting mode (at settings of 45 watt monopolar current) and hemostasis was achieved by coagulation mode electrosurgery unit . We used the electrosurgical generator: Valley lab ForceEZTM-8C, Monopolar: 300 W/300 Ohm, Bipolar 70 W / 70 Ohm. Only one surgical mop used for the incision and were weighed pre- and post-skin incision in a sterile manner using specialized weighing scales. No suction was used while making the incision. At recovery room, all patients received paracetamol (1gm perfalgan) administered by i.v. infusion and on shifting analgesia given on demand according to the patient's need.

Study outcome

Primary outcomes: -

- Wound incision time/ min. (time consumed between beginning of skin incision and opening of parietal peritoneum.
- Wound-related blood loss. (by weighing towels used only for anterior abdominal wall layers incision before and after abdominal wall incision/ gram).

Secondary outcomes

- Postoperative pain (pain score 2-4 hr postoperative).
- Analgesia needed type, number of doses during first 12 hours postoperative.
- Wound infection (sepsis: pus pouring from incision, ecchymosis, seroma, hematoma or gapping)
- Ugly scar formation. Follow up visit was arranged on the 5th day and 40 days after surgery to evaluate scar condition (good – adequate –bad or Keloid) .

Statistical analysis of the data

The IBM SPSS software programme version 20.0 was used to examine the data that was supplied into the computer. (IBM Corporation, Armonk, NY) [7]

A- Descriptive statistics: To determine the central tendency and dispersion of quantitative data, the mean and standard deviation were determined.

B- Analytic Statistics: Comparing groups was prepared utilizing **student's t-test** to compare among two quantitative variables while qualitative data were compared by using **Chi-square(X2) test, and fisher's exact test** was used instead when over than 20percent of cells have predictable frequencies<5. For abnormally quantitative variables, to compare between two studied groups **Mann Whitney test** used. Numbers and percentages were used to describe qualitative data. A p-value of less than 0.05 was used to determine the degree of significance. Tables and graphs were used to report the results.

Results

A total of 120 women were screened for participation in the study. 16 of them were disqualified for failing to satisfy the inclusion criteria and refusing to participate. 14 patients were missed to follow-up in this study because they did not join their second appointment or did not email their incision photo to the first author (S.I).Analysis was done on 90 participants ,45 in each group.

In the present study we reported that electrosurgery decreases wound incision time and wound related blood loss significantly than in scalpel group.

Both groups were comparable regarding age, BMI, and employment status as shown in table (I), 71.1% and 68.9% of studied groups respectively had TAH, and the rest of sample had the surgery for another cause with no statistical difference shown in table (II).

Table (III) presents how significantly electrosurgery decreases wound incision time/ sec and wound related blood loss/grams. Also within the first 12 hours after surgery, the electrosurgery group was also associated with considerably reduced pain levels and the amount of analgesia needed showed in table (IV).

Table (V) shows: Wound infection complicates 6.7%- 2.2% in scalpel and electrosurgery groups respectively with no statistical difference, also in the second visit we observed 2.2%- 0% ugly scar formation in scalpel and electrosurgery groups respectively with no statistical significance.

Regression analysis was done to show which factor greatly affect wound infection. Table (VI) shows: the most significant factor was increasing Body Mass Index (BMI) which increases wound infection. Figure (1): histogram shows significant effect of BMI on wound infection rate in our study.

Table (I) Socio-demographic data among the studied sample

Groups Socio-demographic data	Scalpel group (45)	Electrosurgery group (45)	Significance test	P value
Age /years: mean± SD	43.24±8.291	46.42±12.938	Mann-Whitney test U =814.5	0.11
BMI	29.35± 3.785	30.59±5.954	U=972.00	0.62
Employment: **- House wife** **- Employed**	45(100%) 0(0.0%)	43(95.6%) 2(4.4%)	Chi-Square test X^2=2.045	0.494

Table (II): surgical indication among the studied sample

Groups Surgical indication	Scalpel group (45)	Electrosurgery group (45)	X^2	P value
• **TAH**	32 (71.1%)	31 (68.9 %)		
• **Myomectomy**	6 (13.3%)	7 (15.6%)		
• **Sacropexy**	3 (6.7%)	4 (8.9%)	1.236	0.872
• **Ovarian cyst**	3 (6.7%)	3 (6.7%)		
• **Others**	1 (2.2%)	0 (0%)		

Table (III): Intraoperative data among the studied sample

Groups Intraoperative data	Scalpel group (45)	Electrosurgery group (45)	Test of significance Mann-Whitney test	P value
Wound incision time / sec Mean ±S.D	236.71±94.875	129.62±35.985	U= 303.00	<0.001
Wound related blood loss (grams) Mean±S.D	24.72±9.758	7.39±5.506	U=137.00	<0.001

Table (IV): Effect on post-operative pain among the studied sample

Groups Post-operative pain	Scalpel group (45)	Electrosurgery group (45)	Mann-Whitney test	P value
VAS score (Mean±S.D)				
• **2 hrs.**	9.58±0.78	8.44±1.324	U=536.00	<0.001
• **4 hrs.**	7.69±0.763	7.04±1.021	U=685.00	0.002
Analgesia needed during 1st 12 hrs. postop in number of doses **(Mean±S.D)**	3.02±0.0452	2.16±0.367	U=230.00	<0.001

Table (V): Wound complications among the studied sample

Groups Wound complications	Scalpel group (45)		Electrosurgery group (45)		P value
Wound infection Yes/No	3	6.7%	1	2.2%	
Ecchymosis	1	2.2 %	0	0.0	
Hematoma	1	2.2 %	0	0.0	0.3063
Seroma	0	0	1	2.2 %	
Dehiscence	1	2.2 %	0	0.0	
Wound healing postop					
Ugly scar at day 7	1	2.2 %	0	0.0	1.00
Ugly scar at day 40	1	2.2 %	0	0.0	1.000

P was calculated by using ***Fisher exact test***

Table (VI): Regression analysis of different risk factors which affected the indices of wound infection.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	2.406	.142		16.934	0.0001*
Age (yrs)	.001	.002	.028	0.269	0.788
BMI	-.005	.002	-.362	-3.476	0.001*
wound related blood loss in grams	-.003	.002	-.151	-1.265	0.209
wound incision time (sec.)	1.420E-005	.000	.006	0.051	0.959

a. Dependent Variable: wound infection

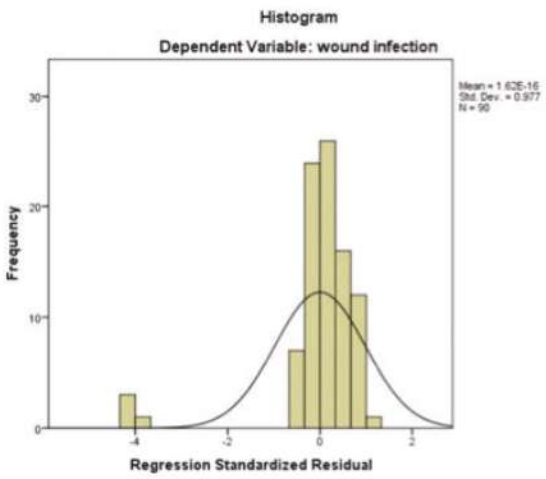

Figure (1): histogram show significant effect of BMI on wound infection rate

Discussion

Given the fact that scalpel utilization is well-known to pose a serious and well-known risk to the surgeon and other team staff, a survey conducted by Assiotis et al. in 2009 showed that only 24 percent of higher surgical trainees in the Great Britain used diathermy for laparotomy skin incisions, while 76 percent used a scalpel .[8]

The belief that electrosurgical instruments augment devitalized tissue within the wound, leading to rising wound infection, scar production, and wound repair delays, has led to aversion to incising skin with electrosurgery. [5] Recent skin incision investigations have found no evidence to support these fears.[9] Electrosurgery units nowadays is becoming more advanced, intelligent and popular since it is effective, precise, easy to obtain, causes minimum post-operative bleeding, and reduces the risk of surface infections. [10]

Recent Cochrane systematic reviews observed low confidence evidence of a distinction in wound infection among scalpel and electrosurgery and advised additional studies to discover the relative effectiveness of scalpel compared with electrosurgery for major abdominal incisions .[11] That is why the present study is conducted to compare the early postoperative and short term wound complication rates among use of scalpel and electrosurgery in transverse abdominal wall incision in elective benign gynecological operations. All participants received 2 gm 2nd generation cephalosporines within 1 hour preoperative per hospital policy.

Our study results demonstrate that use of electrosurgery decreases wound related blood loss and wound incision time signifi-

cantly than in scalpel group. And within the first 24 hours after surgery, the electrosurgery group was also associated with considerably reduced pain levels and the amount of analgesia required. As scalpels are primarily used to produce surgical incisions, its use typically results in skin bleeding, which obscures the operating field and wastes time.

In accordance with our study, several studies (Elbohoty et al., 2015, Pandey et al., 2019, Abdel Aaal et al,2017 &Yadav et al., 2021) compared diathermy versus scalpel in transverse in women undergoing repeated cesarean section , midline abdominal incision and herniorrhaphy in randomized controlled trials, they proved that electrosurgery was superior in terms of wound incision time and wound related blood loss.[10, 12- 14]

Telfer et al., (1993) studied two groups of 101 patients who were performed on using diathermy and scalpel for gastrointestinal resection; the authors observed no significant variation in wound incision time among electrocautery and scalpel. On the opposite, they found a statistically significant difference in blood loss during incision, with the electrosurgery group losing less blood. This variation might be related to the varied types of incisions used (in their study, patients received full-length midline laparotomy incisions). [15] Also They observed no significant variation in wound incision time per wound area among electrosurgery and scalpel in Kearns 2001; Prakash 2015; Siraj 2011.[16-18]

The present study demonstrate that postoperative pain score and doses of analgesia required within first 12-hour post-operative was less in electrosurgery group, that is attributed to good haemostasis less hematoma formation and less bacterial colonization in electrosurgery group.

The findings of Patil et al., 2017 and Nandurkar VS et al., 2018 are consistent with our findings. They investigated the use of a scalpel versus electrocautery for subcutaneous incisions in elective gynaecological surgeries and discovered that postoperative pain was significantly higher in the scalpel group. [19,20] In addition, in agreement with our findings, Chrysos et al.,2005 reported that the electrosurgery group required just half the dose of parenteral analgesics in the postoperative phase, which is consistent with our findings. [21]

In contrast, Parkash et al. (2015) conducted a study in which they compared the electrocautery incision with the scalpel incision in midline abdominal surgery in a double blind randomized controlled trial and found that there was no substantial change in postoperative pain among the two techniques. [17] Their sample included midline incision which characterized by less vascularity, more lengthy extensible wound and expected to more painful than transverse incision also authors included muscle cutting in their incision.

Surgical site infection (SSI) is the most frequent infection acquired while in the hospital among all postoperative consequences. About two-thirds of these infections involve superficial wounds. SSI can develop up to 30 days after surgery, according to the Centers for Disease Control and Prevention (CDC).[22]

We monitored our patients for 40 days post-operative and looked for ecchymosis, seroma, dehiscence, hematoma, or spilling contaminated fluid as signs of wound infection and complications. In our study, scalpel group showed (6.7%) of wound infection versus (2.2%) in electrosurgery group , it was statistically insignificant. We did regression analysis of different risk factors which affected the indices of wound infection, while the significant item was only the increasing of body mass index causing post-operative wound infection, while the age, wound related blood loss and wound incision time show insignificant effect on post-operative wound infection.

In line with our results, a cross-sectional study, participants undergoing midline ab-

dominal incision for uterine malignancies compared to electrosurgery in coagulation mode (433 participants) against cold scalpel (531 participants) for serious wound sequelae (Franchi 2001). In the scalpel group, they reported a higher rate of severe wound complications. However, after adjusting for confounding variables, there were no important change among groups.[23]

Several recent clinical trials and systematic reviews in accordance with our result (Charoenkwan K et al.,2017, Patil et al., 2017, Nandurkar et al., 2018, Talpur et al., 2015 & Eren et al., 2010) reported no significant difference in surgical site infection between the scalpel and electrosurgery skin incision.[11, 19, 20, 24, 25]

In first post-operative visit at 5th day we checked for wound infection and completeness of the process of healing, however, on the second visit, we wanted to double-check the cosmetic appearance of the wound incision, therefore we collected data directly from patients or photographs submitted by participants after 40 days. We could not find any difference between both groups as regard the shape and patient satisfaction of wound.

One of the few studies that looked at cosmetic outcomes as the major endpoint In a double-blind randomized clinical trial, Aird L. N. F. et al. (2015) evaluated the cosmetic outcomes of utilizing the cutting mode of electrosurgery and scalpel for incising abdominal layers at six months after surgery, and they indicated that the obtained results encourage the assumption that diathermy generates a scar with a cosmetic results comparable to scars produced by scalpel.[3]

In accordance with the findings of our study, Kaban et al., 2019 and Douglas A et al., 2013 studies conducted to compare cutting diathermy and scalpel undergoing elective open abdominal general surgical procedures, they use both approaches in the same patient (half of incision done by scalpel and other half by electrosurgery) When comparing Pfannenstiel or midline incisions to scalpel usage in regards of wound repair and scar appearances, they discovered that they were equal in terms of wound repair and cosmetic appearance.[5,26]

We tried to apply blinding as much as possible, blinding of surgeon was not feasible, but allocation concealment was applied and patient were also blind to the type of intervention. One of the limitations in our study is non-blinding of outcome assessor, limited time for follow up, in addition smaller sample size, all these due to limited resources and due to COVID outbreak. The inter-variability between surgeons regarding preferences of skin incision approach was also considered one of our limitations.

In order to improve the method's reliability, further robust trials in this area are required. Adjustment of electrosurgery unit use in abdominal wall incision (cutting or coagulation mode, watt adjustment) should be assessed in such a trial.

Conclusion and recommendation

Nowadays in both laparotomy and minimally invasive laparoscopy, electrosurgery is the most often used type of surgical energy. Proper use of electrosurgery for abdominal wall incision could be practical alternative for scalpel, it saves time ,less painful, reduces wound related blood loss and wound incision time without increase in wound related infection or complications .

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