COMPARING SCISSOR DISSECTION AND ELECTROCAUTERY IN SEROMA FORMATION POST-MASTECTOMY; A PROSPECTIVE RANDOMISED CLINICAL TRIAL

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RESEARCHER'S DECLARATION

Apart from where citations are made, this dissertation is my own original work and has not been presented in any other institution of higher learning.

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ABBREVIATIONS

BCS- Breast Conservation Surgery

EBV- Estimated Blood Volume

H (i)- Pre-operative haemoglobin

H (f)- Post-operative Haemoglobin

Hct (i)- Pre-operative Haematocrit

Hct (f)- Post-operative Haematocrit

KNH - Kenyatta National Hospital

KNH-ERC - Kenyatta National Hospital Ethics and Research Committee

MRM - Modified Radical Mastectomy

RCT- Randomised Controlled Trial

SPSS - Statistical Package for Social Sciences

T (u)- Total Units of Whole blood transfused intra-operatively

UON - University of Nairobi

VEGF- Vascular Endothelial growth Factor

ABSTRACT

Background: Seroma following mastectomy is a common occurrence thus drains are left in situ for at least two weeks. The type of Instrument used during dissection to raise skin flaps has been widely studied and electrocautery has been shown to significantly increase seroma formation compared to other instruments.

Objective: To determine the difference in seroma formation after mastectomy between scissor dissection and electrocautery.

Materials and Methods: This was a single-blinded, prospective randomized controlled study with a sample size of 80 patients. This study was carried out over a period of 6 months. The participants were randomly divided into two groups of 40 each. One group underwent scissor dissection and ties for haemorrhage only while the other was subjected to electrocautery during skin flap fashioning. Data such as operating time and estimated blood loss, seroma presence, total volume of drainage, duration of drainage and drain retention, complications such as infection, wound dehiscence and flap necrosis were noted.

This data was collected on a pre-designed data sheet and entered into a computer and analysed using Statistical Package for Social Sciences (SPSS) for windows version 21.

Results Incidence of seroma formation was 51.3% for electrocautery against 38.7% for scissor which was statistically significant up to 7 days (P=0.0179). The average number of days seroma was drained was 10.65 days in the electrocautery group while 4.92 days in the scissor group and this was found to be significant with a P <0.0001.

The total volume drained on average was 121.2 mls for the scissor group as compared to 233.4 mls in the electrocautery group. Highest volume drained was 585mls in the study group with 760 mls in the control group. There was a significant difference in these outcomes with P<0.0001.

When comparing the complications, 4 (10%) developed Infection, 1 (2.5%) had dehiscence and 1 (2.5%) developed flap necrosis the scissor group and 11 (27.5%), 5 (2.5%) and 1 (2.5%) respectively in the electrocautery group. There was significant difference in the two groups for infection and dehiscence.

Conclusion Scissor dissection reduces seroma formation in terms of duration and volume and reduced complications post operatively making it a viable option during mastectomies in our setup.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background

Modified Radical Mastectomy (MRM) is the mainstay of treatment for early disease and with increasing awareness and health education amongst the developing world there has been an overall increase in surgical treatment[1, 2].

Seroma is defined as accumulation of serous fluid that develops in the dead space post operatively after fashioning of the skin flaps and axillary dissection following mastectomy. This fluid could be blood stained or clear and contains protein and different cells in various proportions[3, 4].

Seroma is the most common complication of surgery of the breast and axilla. Further seroma can cause complications such as wound dehiscence, infection, flap necrosis, delay in adjuvant therapy and may affect reconstruction. It is also associated with patient discomfort, prolongation of hospital stay and may require increased visits for needle aspirations[5].

Several factors have been researched including surgical instruments used to create the skin flaps[6, 7]. The standard technique is use of electrocautery in our setup and although several studies have been carried out to compare scalpel, electrocautery and ultrasonic knife dissection in other parts of the world, no study has been done in our setup. Since it has been shown that electrocautery indeed increases seroma formation, this study therefore seeks to compare seroma formation between scissor dissection and electrocautery.

1.2 Study Justification

Breast cancer is a major health burden and MRM and BCS with or without reconstruction are the main treatment modalities. Seroma is the commonest complication after MRM. Reduced incidence, shorter drain retention and reduction in related complications would be a considerable achievement with regard to surgical outcome, psychological trauma and economic aspects.

Surgical procedure is still attributed as a significant factor and thus a less traumatic approach needs to be considered. Various studies have compared electrocautery to scalpel, harmonic and ultrasonic knife in the Western world but no study regarding this has been done in our region. There is no study to determine whether scissor dissection alone may considerably reduce seroma formation in comparison to the common use of electrocautery.

1.3 Study Objectives

1.3.1 Main Objective

To determine the difference in seroma formation post-mastectomy between scissor dissection and electrocautery techniques during creation of skin flaps.

1.3.2 Specific Objectives

1 To determine the amount of seroma formed post-mastectomy following use of scissors and electrocautery to raise the skin flaps.

2 To determine duration of drainage post-mastectomy following use of scissors and electrocautery to raise the skin flaps.

3 To assess the complications following seroma formation within 21 days.

1.4 RESEARCH QUESTION

Does scissor dissection technique for creating skin flaps reduce seroma formation after mastectomy?

1.4.1 Null Hypothesis

Scissor dissection technique does not reduce seroma formation after mastectomy.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology

The incidence of seroma has been found to vary between 2.5% and 51% after breast and axilla surgery for cancer of the breast from previous studies[6-8].

2.2 Pathophysiology of Seroma

Several analytical studies have been carried out on seroma fluid to help understand the pathophysiology. Watt-Boolsen et al showed that seroma is as a result of an intense and prolonged first phase of wound repair and attributable to an acute inflammatory reaction[9]. Another study showed seroma fluid to have similar compositions of protein and cell count as to lymph and the transection of lymph channels especially in the axillary region are thought to be an important factor in seroma accumulation. It mentioned that the early ambulation of shoulder and ipsilateral arm can act as a pump which forces the fluid into the empty axillary fossa[10].

In another study, Bonnema et al concluded otherwise and reported that the composition of seroma changes with time as on the first post-operative day it was found to contain blood components and by day two it was more lymph like but having more protein, no fibrinogen (thus no coagulation) and different cells[11]. Another study done used an antifibrinolytic agent (tranexamic acid) to establish that it is the fibrinolytic activity of plasmin in seroma that contributes to fluid accumulation and that there is further leakage of fluid from breakdown of fibrin complexes formed around vessels in the region. However they failed to show any significant benefit of using tranexamic acid[12].

An increase in Vascular Endothelial growth Factor (VEGF) in seroma fluid, promotes angiogenesis and a decrease in endostatin which counteracts this was reported thus indicating angiogenesis as the physiologic response to surgery and its role in fluid accumulation[13-15].

2.3 Causes of Trauma during Surgery

There have been several studies using different surgical instruments and techniques for creating the skin flaps to assess the incidence and severity of seroma for breast surgery. The nature and extent of dissection have been shown to directly influence seroma formation. It has been shown that MRM has a higher incidence for seroma formation compared to breast conservation surgery (BCS) and MRM followed by immediate breast reconstruction. This was earlier noted in a study done by Say et al in 1974[16] and later Aitken et al did a

retrospective study on 204 patients that showed an increase in seroma formation with radical mastectomy in comparison with MRM and simple mastectomy[17].

2.4 Surgical Instruments

Electrocautery has been used extensively since it was introduced in 1929[18].Although electrocautery is widely used in clinical practice, its effect on wound healing is poorly defined. The cutting mode of electrocautery produces intense heat and tissue cells explode into steam. Electrocautery uses direct thermal energy and this diffuses deeper into the tissues in comparison to scalpel. This high thermal injury results in large amounts of devitalised tissue and thus increased inflammatory response. Yilmaz et al in 2011using a RCT compared use of ultrasonic dissector to electrocautery and scalpel during surgery and concluded that it has reduced seroma due to less inflammatory response from injury to tissues. They found that ultrasonic dissector had lower amounts of TNF-α and IL-6 levels[19].

A Randomised controlled trial (RCT) in 1998 by Porter et al showed use of electrocautery significantly increases incidence and duration of seroma in comparison to use of scalpel (38% for electrocautery, 13% for scalpel) [20]. This was previously studied by Lumachi et al but had no significant reduction in seroma formation[21]. Another study comparing surgical instruments by Kontos et al showed no difference in seroma after comparing use of harmonic scalpel and electrocautery for dissection[22]

Electrocautery also causes significant lysis of subcutaneous tissue and thus reduces its protective effect. It has been shown that skin flaps created by electrocautery have reduced tension strength, contain more leukocytes, less fibroblasts and collagen and more wound drainage when compared to scalpel use during creation of skin flaps. Electrocautery also results in thrombosis of sub dermal vasculature[23,24].

Surgical experience does not affect seroma after mastectomy is shown in a study done on 164 women with cancer of the breast undergoing mastectomy in 1992. The surgical experience was divided into four cadres i.e. registrar, senior registrar, consultant and professor [25]. Several studies have been conducted and no significant association has been found regarding previous biopsy, type of anaesthesia (general or regional), or preoperative and intraoperative blood transfusion that can increase risk of seroma formation[26].

2.5 Risk Factors Associated With Seroma Formation

In a retrospective study on 1551 patients showed that old age increased incidence of seroma after mastectomy. Tejler et al and Kumar et al reproduced similar results in their respective studies later [27, 28]. However Chilson et al showed results contrary to this and concluded that age was not a factor in increased risk of seroma formation[29].

It has been shown that neo adjuvant chemotherapy might be a significant risk factor in the formation of seroma post mastectomy. Tumour size and lymph node status were studied in 2003 but no significant risk to seroma formation was reported. Further studies on breast size, tumour grade, histological type, specimen weight, and location of tumour have not been shown to have a consistent relation to seroma formation. Also factors such as co-morbid conditions like anaemia, diabetes or smoking have not been found to have a significant relation to seroma formation following breast surgery [30-33].

2.6 Prevention of Seroma Formation

A RCT carried out at UON/KNH in 2011 as a post graduate thesis showed that Freracrylum increased the incidence of seroma but significantly reduced duration of drainage and consequently the days of drain retention[34].

In a RCT by Burak et al in 1997, bovine thrombin was used but no significant difference in seroma formation was reported[35].Based on the concept of seroma being as a result of postsurgical inflammation two trials studying effect of steroid injection on seroma formation are currently ongoing[36,37].

Drains remain a mainstay of seroma management. They have the advantage of draining seroma and thus thought to have a subsiding effect. However drains also have the deleterious psychological trauma of discomfort and pain to the patient, increase hospital stay and serve as potential routes of infection. A variety of drain types and locations and suction have been studied extensively. Two RCTs by Cameron et al and Somers et al showed that leaving no drains increased the incidence of seroma[38,39].

Flap fixation to reduce dead space has been studied both to prevent and reduce seroma formation. A RCT by Coveney et al demonstrated that flap fixation reduces seroma formation and Purushotham et al showed that flap fixation without drainage reduces seroma[40]. In association with this it has been shown that this technique reduces seroma formation in BCS without axillary dissection[41].

Two studies using triangular bandage and collar and cuff to reduce shoulder mobility against postoperative exercise showed no significant reduction in seroma formation after mastectomy[42]. Use of external compressive dressings in a RCT done by O' Head et al showed that in fact these increased the incidence and severity of seroma after mastectomy[43].

2.7 Secondary Complications of Seroma

Seroma leads to delayed wound healing, delays adjuvant therapy, predisposes to sepsis, wound dehiscence, flap necrosis and may result in multiple hospital visits and may require repeated needle aspirations[44-46].

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Area

This study was conducted at the general surgery wards, main theatres and surgical outpatient clinics at Kenyatta National Hospital.

3.2 Study Population

All patients diagnosed with cancer of the breast and scheduled for MRM.

3.3 Study Design

This was a single- blinded, prospective randomised clinical trial carried out from July 2015 to December 2015.

3.4 Sample Size Calculation

The Formula used for Sample size estimation per group[47]:

$$N = \frac{\left(Z_{\alpha/2}\sqrt{2p(1-p)} + Z_{1-\beta}\sqrt{p_1(1-p_1)p_2(1-p_2)}\right)^2}{(p_1 - p_2)^2}$$

Where *n* = sample size,

Z = Z statistic for a level of confidence,

P = expected prevalence

$Z_{\alpha/2}$ = the critical value from normal curve

$Z_{1-\beta}$ = the critical value of β% of type II error.

For β the Z score is about 0.24 for a power of 80% (type two error, the likelihood that you will not detect a difference between P1 and P2 if it is there)

Thus using previous studies[20],the P_1=38% and P_2= 13% at 95% confidence and power of 80%

$$n = \frac{\left[1.96\sqrt{0.4712} + 1.28\sqrt{0.02665}\right]^2}{(0.38 - 0.13)^2}$$

n= 38.7 participants per group

Thus total sample size taken at N= 80

3.5 Sampling Technique

Participants confirmed to be eligible were assigned to two groups by using a computer generated code. Single-blinding was achieved by giving this assignment to a research assistant who did not take part in the final data collection. All the participants were then computed into a plan generator on the computer programme **Randomization.com** using their Initials. This programme first generated a code for each participant, after which it automatically and randomly assigned each participant to either the electrocautery or scissor group. Each participant code and the type of dissection were printed and enveloped. The envelope was sealed and attached to the file which was then opened before surgery in theatre. From thereon only the code was used for data analysis.

3.6 Inclusion Criteria

- All breast cancer patients eligible for MRM
- Patients aged over 18 years
- All patients who consent to participate in the study

3.7 Exclusion Criteria

- Patients requiring any other procedure apart from MRM

3.8 The Surgical Procedure

3.8.1 Counselling and Consent Taking

Patient evaluation and MRM surgeries were performed by Consultants and Registrars in KNH. Evaluation for Cancer of the breast was done using history taking, examination, imaging and histopathological analysis.

After the patients were booked for MRM they were pre-counselled. A comprehensive explanation on what the study entails and its possible outcomes were discussed with respect to the study objectives. During consenting the participants had been explained to about the randomisation process and its importance in the study. Participants were fully informed about the surgical details and any risks. After clarifying and answering any queries from the participants' side, consent was obtained. The counselling and consent process was conducted by the principal investigator and a research assistant with minimum qualification of Bachelor of Medicine and Bachelor of Surgery (MB.ChB).

3.8.2 Details Of Surgery

An oblique skin incision including the tumour and nipple-areolar complex was made using a scalpel for both groups. After this one group underwent the standard electrocautery dissection using EXCELL 350 MCDSe machines at a fixed wavelength of '35' for both 'Cutting and Coagulation' modes. The other group were subjected to dissection using only scissors and ties (Vicryl 2-0 ETHICON) for any haemorrhage for raising the skin flaps. For both groups the flaps were raised superiorly to the clavicle, medially to the sternum, laterally to the edge of the latissmus dorsi and inferiorly to the costal margins and rectus sheath.

Level 1 and 2axillary lymph nodes were dissected and removed by incising the clavi-pectoral fascia along the lateral edge of pectoralis minor muscle. Skin flaps were returned into place and skin closed with interrupted non-absorbable suture (Nylon 2-0 ETHICON) and dressings were applied.

3.8.3 Blood Loss Estimation

This was calculated using a mathematical formula [48]:

Blood loss = {EBV x (H (i) - H (f)) / ((Hct (i) + Hct (f))/2} + (500 x T (u))

This will be calculated using parameters as per appendix 2.

Both groups had two closed system drains of same calibre (Porto-Vac size 18 FG) left in situ through separate stab incisions made in the lower flap posteriorly. One of the drains was directed into the axilla while the other anterior to the pectoralis major. The drainage was measured as per the pre-designed data sheet.

Other variables were noted as per the data sheet. Infection was considered when there was any localised pain or tenderness, swelling, redness and heat with or without drainage of puss within the duration of 21 days and not necessarily confirmed by culture studies. Participants were reviewed at the outpatient clinics at day 7, 14 and 21 after surgery.

3.8.4 Drain Management as Outpatient

The drain management by the patient remained as per the standard for mastectomies at KNH except that they were specifically asked not to drain the fluid until at the clinic where the volumes were measured. As per instructions before discharge, in the event that the collecting flask filled up completely before their arrival at the outpatient clinic, they were to empty it and that was noted as 400/600/800 mls depending on the capacity of the collecting flask. They informed the research team on how many times they emptied the flask and that was

then used to evaluate the total drainage amount for that specific period. The patients were followed up to 21 days after surgery.

3.9 Data Presentation and Analysis

The data was analysed using Statistical Package for Social Sciences (SPSS) for Windows Version 21. Data is presented in forms of tables, pie charts and histograms.No participant was excluded from the analysis after the randomisation process- **intention to treat analysis**. This prevented any bias caused by the loss of participants mostly by cross over, which would have disrupted the baseline equivalence established by random assignment and which may reflect non-adherence to the protocol.

Student's t-test was used to compare continuous variables and chi-square or Fisher's exact test for the categorical variables. A p value <0.05 was considered significant.

3.10 Ethical Considerations

The study commenced upon approval by the department of surgery (UON) and KNH Ethics and Research committee.

A pre-consent counselling of the participants was carried out, after which an informed consent was obtained from each of the participant prior to enrolment into the study. Being hospital patients these participants were not owned by any specific consultant or registrar but those undertaking these surgeries at KNH were informed in advance of the study and requested to abide by the protocol as per the choice of the patient. A few consultants already preferred scissor dissection with minimal use of electrocautery during flap creation and thus both were acceptable methods at KNH.

Patients were not to be coerced to participate if they were unwilling. Non-participation did not affect patient care. Participants were free to withdraw from the study at any point without any effect on their management.

Patients' hospital file numbers were included into the data sheet. This was done so as to allow easy tracing to capture any missed information during data collection.

The data sheets were kept safely with the researcher andconfidentiality and privacy was observed. Electronic data file generated was encrypted with a password only available to the research team. All data sheets will be destroyed after completion of the study.

4.0 CHAPTER FOUR: RESULTS

4.1 Sample Characteristics

A total of 80 participants were enrolled into two categories namely electrocautery and scissor.

Factors such as age, BMI, blood pressure and side of breast were found to have no statistically significant difference on both arms that might have affected the outcomes differently. This is as shown in Table 1.

Table 1: Sample factors

Variable	**Electrocautery (n=40)**	**Scissor (n=40)**	**Test statistic**	**P-value**
Age (mean±sd) in years	53.9± 15.5	52.9± 13.2	t=0.35	0.7273
BMI (kg/m^2)				
Normal weight	12(30.7%)	11(27.5%)		
Overweight	4(10.3%)	18(45%)	X^2=13.18	0.001
Obese	23(59%)	11(27.5%)		
Blood pressure (mm Hg)*				
Normal	19(47.5)	27(67.5%)		
Prehypertension	11(27.5%)	7(17.5%)	X^2=3.28	0.193961
Hypertension s	10(25%)	6(15%)		
Breast site				
Right	20(50%)	17(42.5%)	X^2 =0.45	0.501129
Left	20(50%)	23(57.5%)		

*American Heart Association Blood Pressure Classification

These factors were also independently evaluated to assess if they had any direct influence on seroma formation. There was no statistically significant difference in seroma formation with increasing age. However higher BMI and blood pressure values significantly related to increased seroma formation (Table 2).

Table 2 : Independent Sample Test for Seroma formation

Variable	Number	Overall Seroma formation	T-Test	P-value
Age (mean±sd) in years	53.4±14.3	28.9±36.6	X^2=4.7928	0.5707
BMI (kg/m^2)				
Normal weight	23(29.1%)			
Overweight	22(27.8%)	28.9±36.6	X^2=10.6041	0.0314
Obese	34(43.1%)			
Blood pressure (mm Hg)				
American Heart Association				
Normal	46(57.5%)			
Prehypertension	18(22.5%)	28.9±36.6	X^2=21.1819	0.00029
Hypertension	16(20%)			

With the unequal distribution of number of patients between the groups with regard to the overweight i.e. the overweight group with 4 (10.3%) in the electrocautery group and 18 (45%) in the scissor group and obese categories and positive correlation between BMI and seroma formation (Tables 1 and 2), we conducted a multivariate analysis to see if this unequal distribution had any effect on more seroma formation in the electrocautery group and thus create bias. The analysis did not show any such significant effect of BMI on seroma formation between the two groups with P>0.05

Tumour stage was assessed both Pre operatively and Intra operatively and noted for each group. Most patients were in Stage 3 (T3N1M0) group for both electrocautery and scissor groups. In the electrocautery group, 1 patient had metastatic disease that was discovered post operatively while 1 patient in the scissor group had been assessed to have T0N1M0 lesion. Each group had a patient each with Neo adjuvant chemotherapy. From this there was no significant difference in tumour stage between the two groups (Table 3).

Table 3 : TNM Distribution

Stage	Electrocautery	Scissor	T-test	P-value
0	0	0	X^2= 2.1033	0.551237
1	2	2		
2	16	12		
3	21	26		
4	1	0		

4.2 Surgical Variables

The Duration of Surgery and Estimated Blood loss were noted as the main Intra operative variables. Mean time for surgery in minutes was 93±21 for the electrocautery group and 96.6±19.1 for the scissor group (P-value =0.427).

Blood loss was calculated for each group using the stated formula and the mean for the electrocautery group was 141.6±128.2 mls while found to be 108.2±74mls for the scissor group which wasn't found to be statistically significant.

4.3 Seroma Assessment

The average number of days seroma was drained was 10.65 days in the electrocautery group and 4.92 days in the scissor group (Figure 1) and this difference was found to be significant with a P <0.0001.

The total volume drained on average was 121.2 mls for the scissor group as compared to 233.4 mls in the electrocautery group. Highest volume drained was 585mls in the study group with 760 mls in the control group (Figure 2). There was a significant difference in these outcomes with P<0.0001 (Table 4).

Up to 7 days post operatively, there was no significant difference in number of patients still forming and draining seroma as 12 (30%) in the scissor group and 17 (42.5%) in electrocautery group were actively draining seroma. This however changed at 14 days and 21 days as only 3 (7.5%) and 7 (17.5%), and 0 and 3 (7.5%) for scissor and electrocautery groups were noted respectively. Although there was no significant difference in the presence of seroma however there was a significant difference in the volume of seroma at 7 days post operatively as the scissor group on average drained 6.2±13.5mls while the electrocautery group had 39.8±46.9mls with P<0.0001 (Table 6).

The appearance of the drained fluid was blood stained in 83.3% of the electrocautery group and 55.6% of the scissor group which on average took 2 days to become clear for both groups.

All drains were removed at 14 days post operatively except for the 3 patients who continued to drain seroma till 21 days post operatively. None of the 3 required aspirations after removal of drain on day 21.

Figure 1: Average number of days of Seroma drainage among groups

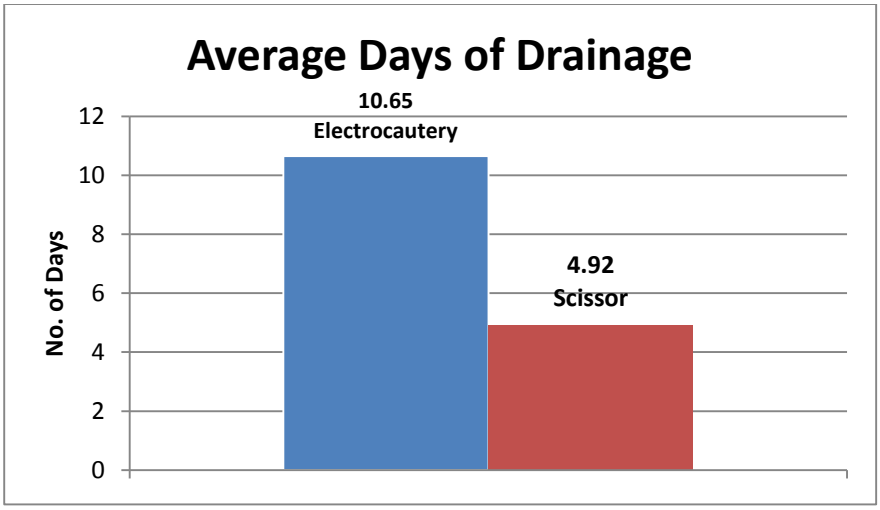

Figure 2 : Total and average volume of seroma drained for each group

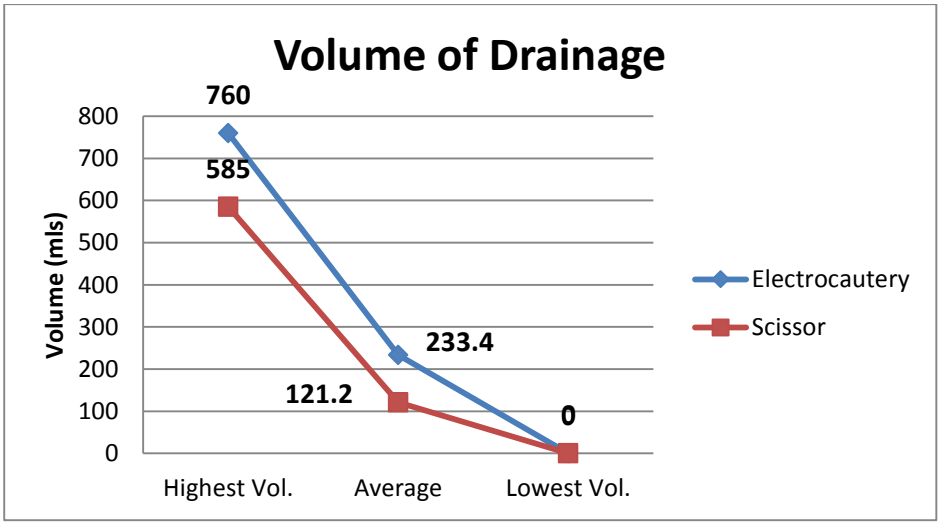

Table 4 : Regression of Seroma Volume

Duration after surgery	Mean±sd	min-max	Electrocautery		Scissor		test	p-value
			n	mean±sd	n	mean±sd		
24 hrs.	53.1±69.9	0-250	40	79.6±81.6	40	26.7±42.4	t= 3.64	0.0005
48 hrs.	34.7±51.5	0-180	40	56.4±62.7	40	13±21.9	t= 4.13	0.0001
72 hrs.	23.3±38.4	0-180	40	39.8±46.9	40	6.9±15.2	t=4.22	0.0001
7 days	20.5±33.6	0-150	37	35.7±41.3	39	6.2±13.5	t=4.24	0.0001
14 days	5.8±13.6	0-60	36	11.9±17.7	38	-	-	-

4.4 Secondary Complications

When comparing the complications, 4 (10%) developed Infection, 1 (2.5%) had Dehiscence and 1 (2.5%) developed Flap necrosis the scissor group and 11 (27.5%), 5 (2.5%) and 1 (2.5%) respectively in the electrocautery group. There was significant difference in the two groups for infection and dehiscence but none in flap necrosis.

5.0 CHAPTER FIVE: DISCUSSION

The primary aim of this RCT was to determine the effect of scissor dissection during skin flap creation on seroma formation after MRM. This was mainly in terms of volume and duration of seroma formed and secondary complications.

There was no statistically significant difference in age when comparing the two groups. Age independently did not have an effect on seroma formation from our study as shown in Table 2. This was previously shown byChilson et al who concluded that age was not a risk factor in seroma formation when he assessed risk factors for seroma post mastectomy[29]. This however remains inconclusive as various studies have reported age has a positive association with seroma formation.

It is important to note that majority of the patients were obese (43.04%), and higher proportion of patients on electrocautery were obese (60%; n=24). Our study shows higher BMI was significantly related to increase in seroma formation independently too. This also was shown by Burak et al who demonstrated a positive association between body weight and seroma formation, Shrivastava et al did a met analytical assessment and stated that BMI does increase risk of seroma [3, 35].

With the possibility of unequal distribution and the positive correlation of BMI a multivariate analysis was conducted and there was no significant effect of BMI to increase seroma formation in electrocautery group alone and thus create bias.

Quite a significant number of patients in both groups had either pre hypertension or hypertension and although there was no significant difference in the two arms, however blood pressure had a positive association with increased seroma formation independently. Kumar *et al* also demonstrated that hypertension was associated with an increase in the incidence of seroma [28].

Intra operative variables such as duration of surgery (93±21minutes for electrocautery and 96.6±19.1 minutes for scissor) and estimated blood loss (141.6±128.2 mls for electrocautery and 108.2±74mls for scissor) were found to be similar in both groups and had no significant effect on seroma formation. Porter et al did an RCT showing less blood loss with electrocautery when compared to scalpel. Our study however shows that there was no significant increase in operating time and blood loss with use of scissor dissection as earlier considered less with electrocautery[17, 20]. Another prospective study looking at surgeon

experience as a factor reported an increase in operating time by 10 minutes increased risk of seroma formation by 35% in terms of volume[25].

Complications such as infection and wound dehiscence were significantly increased in the electrocautery group compared to the scissor. This would be related to the reduced tissue injury and thus less favourable conditions for infections and more favourable for wound healing. Also reduced time of drain retention reduces risk of infection by tracking. Watt-Boolsen et al showed when they described the biochemistry of seroma being inflammatory in natureand thus relating to more inflammation from electrocautery as compared to scissor dissection[9]. Pogson et al reported the volume of seroma being directly related to complications such as wound dehiscence and infection[4]. This was confirmed by Say et al when they did a biostatistical evaluation of complications of mastectomies and found that higher volume of seroma coincided with higher infection rate[16].

With regard to duration of seroma formation, this study shows that scissor dissection results in a significantly lower average number of days of drainage (4.92 days) compared to electrocautery (10.65 days). However a similar study by Porter et al showed use of electrocautery significantly increases incidence but not the duration of seroma in comparison to use of scalpel[20]. Several other studies comparing electrocautery with laser, ultrasonic dissector and harmonic scalpel have shown reduction in incidence and duration of seroma drainage[19-23]. Our study shows use of scissors can help to considerably reduce duration of drain retention from the standard two weeks. With regard to this Barwell et al did a study on how long should drains remain in situ and showed that after 4 days the drains have no obvious benefit in seroma reduction[7]. Thus alleviating risk of drain related complications such as infection and patient inconvenience. However other studies by Cameron et al and Somers et al contraindicated early removal of drains as there is thought to be late seroma formation from 7 to 14 days post operatively[38, 39].

Scissor dissection also significantly reduced the total and average volume of seroma drained. The volume drained on average was 121.2 mls following scissor dissection as compared to 233.4 mls in the control group. Electrocautery shows increase in overall volume of seroma formed. Volume of seroma drained is a significant factor in deciding when to remove the drains. With lower than 30 mls collecting over 24 hours, a drain can be removed safely thus with scissor dissection duration of drain will be significantly reduced. Barwell et al also

reported that volume of seroma in the first 72 hours determines progression of seroma rather than the duration of drain retention[7].

Our study was based on 80 patients from a single centre. A multicentre and larger sample size based study is required to incorporate such practice. Use of local anaesthesia was not standardised for all patients and this might have affected volume changes. Other risk factors such as diabetes, H.I.V./AIDS and histological characteristics of tumour were not assessed. These have been studied earlier by Srivastava V et al, Pogson CJ and Woodworth PA et al but no conclusive evidence of effect on seroma formation has been reported[3, 4, 6].

5.1 Conclusion

Scissor dissection used to create skin flaps during MRM significantly reduced seroma formation in terms of volume and duration and would reduce time of drains in situ and drain related complications. It also reduces other wound related complications. With the other less traumatic instruments not easily available in our setup it would be a more viable option.

Either exclusive or minimal electrocautery during skin flap creation should be encouraged instead of injudicious use, after which the standard duration of drains can be reduced in our setup.

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APPENDICES

Appendix I : Data Sheet

1. Study & file number
2. Age
3. BMI
4. BP
5. Date of admission
6. Date of surgery
7. Tumour Stage:

T	
N	
M	
Neo adjuvant chemotherapy(Yes/No)	

8. Randomization code for instrument used
9. Duration of surgery (minutes)
10. Estimated blood loss (mls)
11. Volume of seroma drained (mls)

Duration after surgery	24hrs	48hrs	72hrs Discharge	7 days	14 days	21 days
Volume						
Comment						

12. Complications (tick if present)
    a) Infection
    b) Dehiscence
    c) Flap necrosis

Appendix II : Estimation of Blood Loss

Blood loss = {EBV x (H (i) - H (f)) / ((Hct (i) + Hct (f))/2} + (500 x T (u))

Where:

1. Estimated blood volume (EBV) is assumed to be 70 cm^3/kg;
2. H(i) and H(f) represent pre and post-operative hemoglobin
3. Hct(i)and Hct(f) represents pre and post-operative hematocrit
4. T (u) is the sum of whole blood, packed red blood cells, and cell saver units transfused.

Study & file number

Weight (Kgs)-

Estimated blood volume (70cm^3/kg)-

Pre-operative Haemoglobin (g/dL)-

Post-operative haemoglobin (g/dL)-

Pre- Operative Haematocrit (%)-

Post-operative Haematocrit (%)-

Total Units of Whole blood transfused intra-operatively-

Appendix III : Consent Forms

Consent Explanation

Study Purpose

This study involves use of either scissors or electrocautery while creating skin flaps during surgery. Usually doctors use electrocautery at Kenyatta National Hospital. We are trying to compare this with use of scissors without using electrocautery and see if it will reduce seroma.

Benefits

The information obtained will help doctors know the influence of surgical technique on this very common complication and other related complications in a bid to improve on treatment and outcome locally.

Confidentiality

All the information which you provide regarding yourself and your condition will be kept confidential and no one but the researchers will see it.

Risks

Both scissor dissection and electrocautery are commonly used in surgery and there are no added risks reported in either method that you will be exposed to.

Follow-up

You will be required to visit the surgical outpatient clinic at KNH on days 7, 14 and 21 after surgery.

CONSENT FORM

I……from……..do agree to be part of the study the risks and benefits of which have been fully explained as by Dr Sameer Pandya. My participation is voluntary and will not be expecting any financial benefits. I will bear the costs of multiple visits to the hospital and any required procedures.

Full name…….

Sign …….

Date ……

Doctor's signature ……..

Left thumb print of participant if unable to sign

FOMU IDHINI

Mimi ..... kutoka ....nimekubali kushiriki katika utafitihuuunaofanywana Daktari Sameer M. Pandya kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Jina la mshiriki……..

Sahihi…….

Tarehe……....

Saini ya daktari……..

Kushoto thumb magazeti ya mshiriki iwapo

hawawezi saini

Appendix IV: KNH/ERC- Letter of Approval

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Ref: KNH-ERC/A/337

3rd August 2015

KENYATTA NATIONAL HOSPITAL APPROVED 03 AUG 2015 KNH/UoN-ERC P.O.Box 20723-00202 NRB

Dr. Sameer M. Pandya
H58/67642/2011
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Pandya

Research proposal – Comparison scissor dissection and Electrocautery in Seroma formation Post-mastectomy; A prospective randomized clinical trial (P242/04/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 3rd August 2015 – 2nd August 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **http://www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
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