Original Article

Comparing the effectiveness of tetracycline sclerotherapy versus placebo in the prevention of postmastectomy seroma among female patients in a tertiary hospital in Southern Nigeria

Alexander Ilo Arekhandia, Raymond Atah Eghonghon, Omorodion Omoruyi Irowa, Clement Odigie Osime

Department of Surgery, University of Benin Teaching Hospital, Benin City, Edo State, Nigeria.

Abstract

Background: Postmastectomy seroma is the commonest complication following mastectomy. It is a cause of significant morbidity for the patient and its management is challenging. Several attempts have been made to prevent or reduce the occurrence of postmastectomy seroma and the results have been inconclusive. Tetracycline is an effective sclerosant and has shown effectiveness in the management of seroma.

Aims: To evaluate the effectiveness of tetracycline sclerotherapy in the prevention of post-mastectomy seroma among women undergoing modified radical mastectomy for breast cancer.

Methods: Seventy-six (76) female patients with histological diagnosis of breast cancer were randomised into 2 groups. Following Auchincloss modified radical mastectomy, both groups had their wounds irrigated with distilled water. Group A in addition, had a suspension of tetracycline instilled. Daily measurements and recording of the drainage volume was done and drain was removed when drainage volume was less than 30mls per day on two consecutive days. The patients were assessed for post-operative pain and other wound complications.

Results: Most patients presented with advanced disease and the predominant histologic sub-type was invasive ductal carcinoma. Seroma was the most common complication followed by wound infection. The incidence of seroma was lower in the tetracycline group 1 (2.6%) than in the control group 5 (13.2%) though this difference did not reach statistical significant (p = 0.089). The application of topical tetracycline did not adversely affect healing of the wound.

Conclusion: Patients that had topical tetracycline applied to their wound following mastectomy had reduced incidence of seroma formation though not statistically significant.

Keywords: Postmastectomy, seroma, sclerosant, sclerotherapy, tetracycline, suspension

Address for correspondence: Dr. Raymond Atah Eghonghon, Department of Surgery, University of Benin/University of Benin Teaching Hospital, Benin City, Edo State, Nigeria.
Email: raymond.eghonghon@uniben.edu
Phone: +2348058013152

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INTRODUCTION

Breast cancer is the most commonly diagnosed malignancy affecting women worldwide and a leading cause of cancer-related deaths in women globally.[1] It is the commonest female malignancy in sub-Saharan Africa with an incidence of 20 - 25 per 100,000 women.[2] In Nigeria, it is also the commonest female malignancy.[3]

Optimal treatment outcome for breast cancer depends on early diagnosis and an individualized multimodal approach to management. Current therapies in treating breast cancer include one or a combination of surgery, chemotherapy and radiotherapy.[4]

Current surgical options of treatment include breast conserving surgery and mastectomy with or without axillary lymph node dissection depending on the stage of the disease.[5,6]

Seroma is the most common complication following mastectomy. It is the collection of serous fluid in the dissection bed following mastectomy and/or axillary dissection.[7] Although not a life threatening complication, it is a source of significant morbidity for the patient. Its sequelae include increased rate of surgical site infection, flap necrosis, wound dehiscence and the need for further surgical intervention. It also results in increased hospital stay and delay in commencement of adjuvant therapy.[8,9]

The pathogenesis of seroma has not been fully elucidated. One hypothesis for seroma formation and perhaps the most widely accepted is that impairment in lymphatic drainage results from surgical disruption of lymphatic channels during mastectomy. Consequently, there is accumulation of liquid that forms seroma. This hypothesis is supported by studies in which the analysis of the drained liquid was found to be comparable to lymph.[10] Other factors that have been proposed to be involved in the pathogenesis of seroma include fibrinolytic activity and accumulation of acute inflammatory exudates in response to surgical trauma and acute phase of wound healing.[7]

The management of seroma is challenging to the surgeon. It is ideally managed by repeated needle aspiration of the collection to seal the skin flaps against the chest wall. Seroma aspiration is not without risks as repeated aspirations potentially introduce infection. In reconstructive surgery, where implants are used, this could result in total implant failure.[9] Sometimes seroma can persist despite repeated aspirations and become longstanding. Some researchers have explored techniques in which agents such as talc and tetracycline are introduced into the seroma cavity to promote adhesion of flaps to the chest wall. When these methods fail surgical intervention with either scoring or capsular excision may be indicated.[11]

Several attempts have been made to prevent or reduce the occurrence of postmastectomy seroma including moderate use of electrocautery, suturing the skin flaps to underlying muscle, application of mechanical pressure garment, use of various types of drains and application of sclerosants and sealants, with all of these producing variable results.[12] Tetracycline is an antibiotic that is commonly used in several aspects of surgery as a sclerosant. This study was carried out therefore, to determine the effectiveness of tetracycline sclerotherapy in preventing postmastectomy seroma among female patients undergoing modified radical mastectomy for breast cancer at the University of Benin Teaching Hospital, Benin City, Nigeria.

MATERIALS AND METHODS

The study was a prospective randomized comparative study carried out at the department of surgery, University of Benin Teaching Hospital, Benin City, Nigeria between July 2022 and October 2023.

Ethical approval for the study was obtained from the Ethics Committee of the University of Benin Teaching Hospital.

Seventy-six consecutive adult female patients with histologic diagnosis of breast cancer scheduled for Auchincloss modified radical mastectomy in the General surgical unit of the University of Benin Teaching Hospital were randomly distributed into groups A and B using a computer-generated table of random numbers. Preoperatively the patients were evaluated in the out-patient clinic and socio-demographic data, anthropometric measurements, side of the lesion and histology were noted. At completion of the procedure, the wounds of all the patients were irrigated with distilled water and suctioned. In group A patients, a closed passive drain designed using a size 18FG feeding tube made of plastic was used. Multiple fenestrations were made in the segment of the tube to be placed within the wound. The tube was passed through a separate stab incision on the lateral aspect at the level of the 5th intercostal space and extended through the axilla to the medial side

of the wound. The drain was anchored to the skin using Nylon 1 sutures. The external end of the tube was capped. A suspension of 2g of tetracycline manufactured by Fidson Healthcare PLC in 100mls of normal saline was applied to the chest wall and the underside of the skin flaps using a wet gauze and the wound was closed with Prolene 0 interrupted stitches, and a sterile dressing applied. After 30minutes the drain was then opened and connected to a drainage bag manufactured by Huaian Angel Medical Instruments Co., Limited, Jiangsu, China. In group B patients, after the wound was irrigated with distilled water and suctioned a fenestrated size 18FG feeding tube was passed as in the group A patients and capped. 100mls of normal saline was applied to the chest wall and the underside of the skin flaps using a wet gauze. The wound was closed with Prolene 0 interrupted stitches and a sterile dressing applied. After 30 minutes the drain was then opened and connected to the drainage bag.

Analgesics were commenced post operatively based on the unit's routine pain management plan. Post-operative pain was assessed on post op day 1 using the visual analogue score (VAS). Daily measurement and recording of the drainage volume was done by a research assistant using a calibrated jar and drain was removed when drainage volume was less than 30mls per day on two consecutive days. The wound dressing was changed on days 3, 7, 10 and as indicated. The wound was inspected for infection as evidenced by clinical signs of cellulitis or purulent discharge. Seroma was defined as any clinically apparent fluid collection under the mastectomy flaps after removal of drain. Surgical site infection was defined by pain, erytherma, and seropurulent discharge from the wound.

Data analysis was done using SPSS (Statistical Package for Scientific Solution) Version 23, manufactured by IBM, Chicago, USA. Descriptive statistics was used for the demographic information in both study arms - frequencies, mean, percentages and standard deviation. We assume a normally distributed data and so a students' t-test was used to compare variables between the two groups while the primary outcome measure between the two groups were compared using Chi-square test. The Fishers exact test was also used to compare other outcome measures. A p-value of .05 or less was considered statistically significant.

RESULTS

Seventy-six female patients with a diagnosis of breast cancer were recruited for this study with 38 patients randomly allocated into two groups. Their age ranged from 31 to 85 years with a mean age of 47.0 ± 10.7 years. The mean body mass indices were comparable in both groups, 26.7±3.5 kg/m2 and 25.9±3.3 kg/m2 for the control and tetracycline groups respectively ($p>0.05$).

Fourteen (18.4%) of the patients had hypertension while 6 (7.9%) patients had diabetes mellitus. Most of the patients presented with locally advanced disease (73.7%) and metastatic disease (15.8%). Only 10.5% of patients presented with early disease. Seventy (92.1%) of the participants had histologic diagnosis of invasive ductal carcinoma, 3 (3.9%) invasive lobular carcinoma, 1 (1.3%) mucinous adenocarcinoma, 1 (1.3%) metaplastic adenocarcinoma and 1 (1.3%) carcinoma in-situ. Breast cancer more commonly involved the left breast 43 (56.6%) than the right.

The difference in mean weight of the mastectomy specimen in the study group (1417.9 grams ± 417.7) compared to the control group (1264.5 grams ± 437.6) was not statistically significant ($p>0.05$).

The patients that had topical tetracycline had a higher mean cumulative drainage volume compared to the control group. The difference was statistically significant (747.7mls vs 555.4mls; $p < 0.050$). Six (7.9%) of the participants had seroma, 5 (6.6%) had wound infection, 3 (3.9%) had wound dehiscence and 1 (1.3%) had flap necrosis. The incidence of seroma in the control group was higher than the treatment group (13.2% vs 2.6%; $p=0.089$).

Table 1: Comparison of demographic characteristics of patients in both groups

Variable	All participants N = 76 (%)	Control Group n = 38 (%)	Treatment Group n = 38 (%)	Test statistics	p value
Age (years)					
Mean (SD)	47.0 (10.7)	47.8 (11.4)	46.3 (10.0)	t = 0.598	p = 0.551
Co-morbidity					
DM	6 (7.9)	2 (5.3)	4 (10.5)		
Hypertension	14 (18.4)	9 (23.7)	5 (13.2)		
Nil	56 (73.7)	27 (71.1)	29 (76.3)	F = 1.845	p = 0.421
BMI (kg/m2)					
Mean (SD)	26.3 (3.4)	26.7 (3.5)	25.9 (3.3)	t = 0.916	p = 0.363
Bra Cup Size					
Mean (SD)	38.7 (2.9)	38.6 (3.1)	38.8 (2.8)	t = -0.306	p = 0.761

Table 2: Breast involved, histologic diagnosis and stage of the disease

Variable	All participants N = 76 (%)	Control Group n = 38 (%)	Treatment Group n = 38 (%)	Test statistics	p value
Breast involved					
Right	33 (43.4)	16 (42.1)	17 (44.7)	$\chi^2 = 0.054$	p = 0.817
Left	43 (56.6)	22 (57.9)	21 (55.3)	(df=1)	
Histologic diagnosis					
Carcinoma insitu	1 (1.3)	0 (0.0)	1 (2.6)		
Invasive ductal carcinoma	70 (92.1)	36 (94.7)	34 (89.5)		
Invasive lobular carcinoma	3 (3.9)	1 (2.6)	2 (5.3)		
Mucinous adenocarcinoma	1 (1.3)	1 (2.6)	0 (0.0)		
Metaplastic cancer	1 (1.3)	0 (0.0)	1 (2.6)	F = 3.273	p = 0.707
Stage of disease					
Early	8 (10.5)	5 (13.2)	3 (7.9)		
Locally advanced	56 (73.7)	29 (76.3)	27 (71.1)	$\chi^2 = 1.905$	p = 0.386
Metastatic	12 (15.8)	4 (10.5)	8 (21.0)	(df=2)	
Lymph Node Involvement					
No	8 (10.5)	5 (13.2)	3 (7.9)	$\chi^2 = 0.559$	p = 0.455
Yes	68 (89.5)	33 (86.8)	35 (92.1)	(df=1)	

Table 3: Peri-operative variables of patients in both groups

Variables	All participants N = 76 (%)	Control Group n = 38 (%)	Treatment Group n = 38 (%)	Test statistics	p value
Duration of surgery (mins)					
Mean (SD)	118.4 (10.6)	116.3 (11.1)	120.5 (9.8)	t = 1.748	p = 0.084
Weight of Specimen (g)					
Mean (SD)	1341.2 (431.9)	1264.5 (437.6)	1417.9 (417.7)	t = 1.563	p = 0.122

Table 4a: Pain and drainage outcomes

Variables	All participants N = 76 (%)	Control Group n = 38 (%)	Treatment Group n = 38 (%)	Test statistics	p value
Time of administration of first dose of analgesia (mins)					
< 30	3 (3.9)	0 (0.0)	3 (7.9)		
30 – 60	8 (10.5)	3 (7.9)	5 (13.2)		
61 – 120	25 (32.9)	13 (34.2)	12 (31.6)	$\chi^2 = 3.940$	p = 0.268
>120	40 (52.6)	22 (57.9)	18 (47.4)	(df = 3)	
VAS 1st day post-op					
4	11 (14.5)	5 (13.2)	6 (15.8)		
5	19 (25.0)	12 (31.6)	7 (18.4)		
6	35 (46.1)	19 (50.0)	16 (42.1)		
7	11 (14.5)	2 (5.3)	9 (23.7)		
Mean (SD)	5.6 (0.9)	5.5 (0.8)	5.5 (0.8)	t = -1.265	p = 0.210
Drainage volume (ml)					
Mean (SD)	651.6 (142.2)	555.4 (98.8)	747.7 (110.5)	t = -7.994	p = 0.000
Day of drain removal					
Mean (SD)	7.9 (1.3)	7.2 (1.3)	8.5 (1.1)	t = -4.733	p = 0.000

Table 4b: Complications and recovery

Variables	All participants N = 76 (%)	Control Group n = 38 (%)	Treatment Group n = 38 (%)	Test statistics	p value
Seroma formation					
No	70 (92.1)	33 (86.8)	37 (97.4)	$\chi^2 = 2.895$	p = 0.089
Yes	6 (7.9)	5 (13.2)	1 (2.6)	(df = 1)	
Number of times aspirated (n = 6)					
2	2 (33.3)	1 (20.0)	1 (100.0)		
3	1 (16.7)	1 (20.0)	0 (0.0)		
4	2 (33.3)	2 (40.0)	0 (0.0)		
5	1 (16.7)	1 (20.0)	0 (0.0)	F = 3.011	p = 1.000
Wound Infection					
No	71 (93.4)	36 (94.7)	35 (92.1)		
Yes	5 (6.6)	2 (5.3)	3 (7.9)	F = 0.214	p = 1.000
Flap Necrosis					
No	75 (98.7)	38 (100.0)	37 (97.0)		
Yes	1 (1.3)	0 (0.0)	1 (3.0)	F = 1.013	p = 1.000
Wound Dehiscence					
No	73 (96.1)	36 (94.7)	37 (97.0)		
Yes	3 (3.9)	2 (5.3)	1 (3.0)	F = 0.347	p = 1.000
No. of wound dressings					
1 – 5	69 (90.8)	35 (92.1)	34 (89.5)		
6 – 10	3 (3.9)	2 (5.3)	1 (2.6)		
> 10	4 (5.3)	1 (2.6)	3 (7.9)		
Mean (SD)	4.0 (3.1)	3.7 (2.3)	4.7 (3.7)	t = 1.415	p = 0.161
Day of stitch					

removal					
9	3 (3.9)	2 (5.3)	1 (2.6)		
10	38 (50.0)	20 (52.6)	18 (47.4)		
11	20 (26.3)	9 (23.7)	11 (28.9)		
12	9 (11.8)	5 (13.2)	4 (10.5)		
13	3 (3.9)	2 (5.3)	1 (2.6)		
14	3 (3.9)	0 (0.0)	3 (7.9)		
Mean (SD)	10.7 (1.1)	10.6 (0.9)	10.9 (1.2)	t = -1.032	p = 0.305
Duration of hospital stay					
≤ 7	5 (6.6)	4 (10.5)	1 (2.6)		
> 7 – 14	59 (77.6)	27 (71.1)	32 (84.2)		
> 14	12 (15.8)	7 (18.4)	5 (13.2)		
Mean (SD)	12.4 (2.7)	11.9 (2.8)	12.8 (2.4)	t = 1.504	p = 0.137

Test statistics: t = t test, χ^2 = Chi-square test F = Fisher's exact test

DISCUSSION

Assessment of pain on the first day post mastectomy revealed comparable pain levels in both arms of the study. In a study conducted by Rice et al.,[13] no significant difference in pain levels was observed between the control and tetracycline groups during the immediate postoperative period (p = 0.453). Similarly, Hokkam et al.[14] reported no substantial difference in the severity of pain (p > 0.05) between the control and treatment groups when tetracycline was employed in the management of post-mastectomy seroma.

Topical application of tetracycline has been shown to induce inflammatory response.[15] In addition, pain is one of the most commonly reported complications that occurs following tetracycline pleurodesis for pleural effusion.[16,17] This is contrary to the finding in this study. Injury to sensory nerves during mastectomy causes loss of sensation to the flap and adjoining chest wall and may account for the reason why topical administration of tetracycline did not cause increased sensation of pain in the treatment group.

The patients that had topical tetracycline had a higher mean cumulative drainage volume compared to the control group (p < 0.05). This is in keeping with findings by Rice DC et al[13] who reported a higher mean cumulative drainage volume in patients that had topical tetracycline compared to the control group (901mls vs 689mls). Tetracycline has been demonstrated to induce intense inflammation and causes early exudative effusion when applied topically into the pleural space which could have accounted for the higher mean cumulative drainage volume in the treatment group.[15] The mean day of drain removal in the control group was earlier compared to the study group and the difference was statistically significant (7.2 days ± 1.3 vs 8.5 ± 1.1; p < 0.050). This can be attributed to the increased exudative effusion caused by tetracycline application and consequent increase in post-operative fluid drainage from the wound.

Seroma was the commonest complication and occurred in 7.9% of the total participants. Seroma is the most frequent complication seen after mastectomy and axillary surgery with an incidence of 3 – 85%.[18] Ogundiran et al[19], Hashemi et al[9], Lumachi et al[20], and McCaul et

al[21] all reported seroma as the most common post-operative complication following mastectomy. Disruption of lymphatic channels during mastectomy is an important reason for this finding. The incidence of seroma was higher in the control group (13.2%) than in the tetracycline group (2.6%). This difference however did not reach statistical significance (p = 0.089). Tetracycline induces inflammation and fibrotic response that seals the dead space. The sclerotherapeutic effect of tetracycline may account for the reduced incidence of seroma in the treatment group. Conversely, Rice et al[13] reported a higher incidence of seroma in the tetracycline group compared to the control. The observation of a reduction in the rate of seroma formation in patients who received tetracycline in this study may be attributed to the use of increased dose of tetracycline. Two grams of tetracycline was used in this study as against 1g by the other researcher. While the only patient in the treatment group that developed seroma had the effluent aspirated on two occasions, the patients in the control group had 2 to 5 aspirations. This meant more clinic visits and the consequent financial burden on the patient.

Although the incidence of wound infection is comparable in both groups, more patients in the tetracycline group – 3 patients (7.9%) – developed wound infection postoperatively compared to 2 patients (5.3%) in the control group. The mean day of drain removal for patients in the tetracycline group was latter than for those in the control group. The presence of wound drain for a longer duration in the tetracycline group could have accounted for the increased number of participants with surgical site infection.

There was no statistically significant difference in the occurrence of other post-mastectomy complications in the control and tetracycline groups; wound dehiscence (p = 1.000), flap necrosis (0% vs 3.0% p = 1.000). The control and tetracycline groups had comparable mean days of suture removal (10.6 ± 0.9 vs 10.9 ± 1.2; p = 0.305). The mean duration of hospital stay in the control group was marginally shorter than that of the tetracycline group, although this difference did not reach statistical significance (11.9 ± 2.8 vs 12.8 ± 2.4; p = 0.137). Consequently, the administration of tetracycline neither adversely impacted the wound's healing process nor resulted in a delay in hospital discharge.

LIMITATIONS

Seroma was not objectively assessed using ultrasonography. This may have introduced bias.

Long term follow-up of the participants to detect those that may have had delayed seroma formation and other complications was not feasible due to the short duration of the study.

The relatively small sample size may affect the generalizability of the findings from this study.

CONCLUSION

The findings from this study showed a decreased incidence of seroma formation in patients who received tetracycline solution application to the mastectomy bed compared to the control group. Although this trend may have clinical relevance, it did not reach statistical significance. Conversely, patients who underwent tetracycline solution application experienced increased early exudative drainage from their wounds. Notably, the use of tetracycline solution did not result in a substantial difference in complication rates.

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Conflict of Interest:

There are no conflicts of interest.

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