CASE CONTROL STUDY: SEROMA CONTROL USING AXILLARY EXCLUSION TECHNIQUE

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ABSTRACT

Introduction: Seroma is the most common problem occurring after mastectomy, it's viewed as necessary evil rather than serious complication, as it usually resolves within a few weeks. Methods: this is a case-control study including 40 patients divided into 2 groups, Group A cases (n=15) and Group B control (n=25). In group A axillary exclusion technique was implied and 2 separate drains were left in the axilla and mastectomy flap, whilst in group B mastectomy wound was closed using conventional way and the mastectomy cavity and axillary cavity were continuous, 2 drains were placed in the surgical site. Total drain outputs were recorded for all patients prior to drain removal. Results: There was significant statistical difference between the cases and controls regarding the total drain amounts collected in breast drain and axilla drain (p < 0.05), the mean total output of axilla drains of cases being 80 ml with higher mean among controls which was 128 ml. Mean of total amount of breast drains of cases being 112.67 ml higher than the mean among controls which was 161.8 ml. The mean amount of output in both breast and axillary drains was significantly less among cases being 192.67 ml and was 289 ml among controls for both drains. Conclusion: Axillary exclusion technique despite taking longer time is easy to learn, feasible and safe. It effectively reduces morbidity and pain after axillary node dissection allowing rapid recovery, resuming normal activities and good quality of life in comparison with classic surgery with suction drainage.

INTRODUCTION

Several approaches to reducing seroma volume, such as the use of a laser scalpel, a compression dressings, multiple axillary drains, high intensity vacuum drainage, fibrin glue and delayed shoulder exercises, have all been tested in randomized trials but failed to demonstrate any impact on axillary seroma formation. Over 15 years ago, Hamy and colleagues described a surgical technique to close the axilla after an axillary lymphadenectomy without using a drain. This simple technique consisted of padding the axilla to eliminate dead spaces and was derived from that developed by Aitken et al. for seroma prevention after mastectomy and lymphadenectomy.

The axillary exclusion technique is one of these approaches, it involves suturing the superior mastectomy skin flap down to the free edge of pectoralis major muscles and the lateral chest wall muscles using a continuous stitch and then placing 4 - 6 interrupted sutures between pectoralis major and minor to reliably exclude the axillary fossa from the remainder of the mastectomy cavity.

A pressure dressing is applied to all wounds. Vacuum suction drains were placed at surgery in all patients with the tip placed within the mastectomy cavity, and total drain outputs were recorded.

The presence and severity of seroma was recorded, drains remained in situ for 4-7 days at the discretion of the community district nurse. At the time of drain removal, total drain output was measured and recorded, and number of patients that developed seroma was decided.

In our study, the axillary exclusion was done, two drains were inserted; one in the axillary cavity and the other in the mastectomy wound cavity and drain output was recorded on the 1st, 4th and 6th day post-operative to assess the effectiveness of the technique.
**Patient and Methods**

**Patients distribution:** All the patients in this study were randomly divided into 2 groups; group (A) & group (B)  

After mastectomy, at the point of skin closure, patients either had axillary “exclusion” or conventional closure.  

**Group (A) (Axillary Exclusion group):** 15 patients had MRM and axillary exclusion technique. Two separate suction drains were placed at surgery in all patients with the tip placed within the mastectomy cavity, and the other drain with tip in the axillary fossa and total drain outputs were recorded for all patients prior to drain removal.  

**Group (B) (Conventional group):** 25 patients had MRM and the incision was closed in the conventional way; the axillary and the mastectomy cavities were continuous. Two suction drains were placed at surgery in all patients one with tip in the axillary fossa and the other drain with tip in the mastectomy cavity and total drain outputs were recorded for all patients prior to drain removal.

**Surgical Procedure**

- A single dose of intravenous antimicrobial prophylaxis was administered within 60 minutes prior to the surgery to ensure adequate drug tissue levels at the time of initial incision.  
- All surgical procedures were performed under general anesthesia.  
- All the patients had Modified Radical Mastectomy.  

**Operative steps**

- The patient was positioned supine, tilted away from the surgeon, with her arms extended on arm boards at ≤90° abduction from the chest wall.  
- The outline of the breast was marked and the medial and lateral end points of the breast were identified.  
- A solution of diluted epinephrine hydrochloride in lactated ringer was infused to the avascular plane to facilitate dissection and minimize blood loss during surgery.  
- Incision was made and flaps are raised to the previously identified borders of the breast and making sure the flaps are viable, this was insured by making sure that viable subcutaneous tissue and superficial vasculature without compromising removing the entire mammary gland.  
- The flaps were approximately 5mm in thickness and the plane was identified by careful retraction of the skin with adequate counteraction to identify the avascular plane and this was done by scalpel or electrocautery.  
- The flaps were raised to the borders of the breast and the pectoralis fascia was divided and removed.  
- Axillary dissection of level I and II lymph nodes with the same incision by opening the clavipectoral fascia.  
- The axillary vein was identified and lymphatics were tied or cauterized, careful steps to preserve the vein and the thoracodorsal bundle together with the Long Thoracic nerve.  
- Often, several branches of the intercostobrachial nerve were identified superficially during axillary dissection. The extent of axillary dissection was to the axillary vein superiorly, the medial border of pectoralis minor medially, the level of the fourth intercostal space inferiorly and the border of latissimus dorsi laterally, with preservation of the thoracodorsal neurovascular bundle, long thoracic and if possible intercosto brachial nerves.  

- A level I and II ALND was performed in all patients with a combination of blunt and careful sharp dissection.  
- Also, level III nodes were assessed intraoperatively and dissection of it if enlarged and palpable.  
- After the specimen is removed, the wound is irrigated with warm saline, and proper meticulous hemostasis is obtained.  

- In group A, the axilla was closed by axillary exclusion technique; the technique involved suturing the superior mastectomy skin flap down to the free edge of pectoralis major and the lateral chest wall using a continuous 2-0 vicryl stitch and then placing 4 to 6 interrupted sutures between pectoralis major and minor to reliably exclude the axillary fossa from the remainder of the mastectomy cavity. Two suction drains are inserted, one with tip in the axillary fossa and the other drain with tip in the mastectomy cavity.  
- The incision is then closed, by closure of Scarpa’s fascia by absorbable 3-0 Vicryl interrupted sutures and the skin was closed with stapler.  
- In group B, the axilla is closed conventionally in continuous with the mastectomy cavity by closure of Scarpa’s fascia by absorbable 3-0 Vicryl interrupted sutures and the skin was closed with stapler.  
- Tight dressings were applied over the axillary and breast wound. There is no need for external compression dressing but a light fluff dressing is placed until the following morning.  
- The excised axillary specimen and tumor specimen were sent to the pathologist to be examined. The data were to be reported upon (The pathological nature & the histological grading of the tumor, the number of LNs in axillary dissection specimen and the number of dissected axillary LNs affected by metastasis).

![Fig 1 Intra-operative photograph showing the technique: Suturing of superior mastectomy flap to pectoralis major.](image)
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Case Control Study: Seroma Control Using Axillary Exclusion Technique

Postoperative Follow-up
All patients were discharged after an observation period of 24 hours to be followed up clinically in the outpatient clinic for one month after surgery divided into four visits as follow:

- The first visit was at the 4th postoperative day (first evaluation was made).
- The second visit was at 6th postoperative day where drains are usually removed.
- The third visit was at 14th postoperative day where skin staples are removed.
- The fourth visit was at one month after surgery for the final follow-up before the start of adjuvant chemotherapy and/or radiotherapy.

For both groups of patients during each post-operative visit should assess and evaluate the following:

- Clinical examination of the axilla to detect axillary seroma formation and drain readings
- Patient’s own records of previous drain readings
- Post-operative pain & analgesia requirement.
- Range of shoulder movement & resuming normal activities.
- Clinical examination of the wound and site of the drain to detect signs of inflammation and assess the healing process.
- Early post-operative complications such as hematoma and wound infection (fever, hyperemia, tenderness, swelling and pyogentic discharge at the incision site).
- Patient satisfaction.

Evaluation and assessment of the outcomes

Primary outcomes measures
- Seroma formation and drain readings, axillary seroma was assessed clinically and by amount of fluid in the drain on the visit itself and what the patient has recorded at home. It is considered appreciable if readings declined day by day postoperatively.
- Healing process and wound-related complications such as (hemorrhage, hematoma and wound infection).
- Post-operative pain & analgesia requirement.

Secondary outcomes measures
- Range of shoulder movement (external rotation and abduction) and resuming normal activities.
- Quality of life and patient satisfaction.

RESULTS
This is a Descriptive Prospective case control Study conducted on 40 patients with breast cancer who were admitted to the breast surgery department and underwent Modified Radical Mastectomy during the year 2019.

The significance level was set at P ≤ 0.05. Statistical analysis was performed with IBM SPSS Statistics Version 23 for Windows.

Age, body mass index and other co-morbidities were comparable between groups. Table (1) shows Age, BMI and number of diabetic patients in the study. There was no significant statistical difference between the cases and controls regarding age, BMI and D.M (p > 0.05), Mean age of cases

Postoperative care involves
Routine postoperative care according to the hospital protocol including (Analgesia, Early patient mobility eating and drinking) were followed till patient discharge.
being 58.2 years old and a younger age mean of controls which is 52.72 years old.

Mean BMI of cases being 32.33 kg/m² and a similar BMI mean of controls which is 31.56 kg/m². Percentages of diabetics of cases were 6.67% and 12% of controls.

Types of pathology were included invasive ductal carcinoma, ductal carcinoma in situ (DCIS), invasive lobular carcinoma, mixed invasive ductal/lobular carcinoma, mucoid carcinoma and low-grade mucinous carcinoma. Sizes of tumor varied from < 2 cm (10 patients), 2-5 cm (35 patients) and > 5 cm (2 patients).

Table 1 Representation of demographic data.

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Group A (n = 15)(100%)</th>
<th>Group B (n = 25)(100%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.20 ± 13.5</td>
<td>52.72 ± 11.95</td>
<td>0.056</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>32.33 ± 3.72</td>
<td>31.56 ± 4.85</td>
<td>0.599</td>
</tr>
<tr>
<td>D.M</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetic (n, %)</td>
<td>1 (6.67)</td>
<td>3 (12)</td>
<td>0.066</td>
</tr>
<tr>
<td>Non diabetic (n, %)</td>
<td>14 (93.33)</td>
<td>22 (88)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2 Descriptive and comparative statistics of amount of seroma collected in breast and axilla drains in different days post operatively.

<table>
<thead>
<tr>
<th>Drain data</th>
<th>Group A (n = 15)(100%)</th>
<th>Group B (n = 25)(100%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast drain D*1 (ml)</td>
<td>59 ± 16.92</td>
<td>84 ± 31.23</td>
<td>0.002</td>
</tr>
<tr>
<td>Mean ± SD (range)</td>
<td>38.67 ± 15.29</td>
<td>49.40 ± 22.52</td>
<td>0.081</td>
</tr>
<tr>
<td>Breast drain D6(ml)</td>
<td>15 ± 11.18</td>
<td>28.40 ± 20.65</td>
<td>0.011</td>
</tr>
<tr>
<td>Mean ± SD (range)</td>
<td>48 ± 11.92</td>
<td>62 ± 21.9</td>
<td>0.010</td>
</tr>
<tr>
<td>Axilla drain D1 (ml)</td>
<td>24.33 ± 11.63</td>
<td>42.40 ± 19.21</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean ± SD (range)</td>
<td>7.67 ± 7.04</td>
<td>23 ± 15.07</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Significant at P ≤ 0.05  *D= postop day

There was significant statistical difference between the cases and controls regarding drain amounts collected in breast drain and axilla drain (p < 0.05).

Mean amount of breast drain on day 1 of cases was 59 ml; it was higher among controls which was 84 ml.

No statistical significance was found when comparing drain amount of breast in D4 in both cases and controls (p >0.05) whereas mean of breast drain on day 4 of cases was 37.67 ml and of controls was 49.40 ml.

On day 6, the mean amount of breast drain of cases being 15 ml, showed considerably less values than among controls, which was 28.4 ml.

Mean of the axilla drain on day 1 of cases was 48 ml and it was higher among controls with value of 62 ml. On day 4, the mean amount of axilla drain of cases was 24.33ml and the mean of controls was 42.4 ml. On day 6 mean amount of axilla drain of cases being 7.67 ml and it was also considerably higher for the control cases which was 23 ml.

Significant statistical correlation between BMI and breast drain amount was found with Pearson correlation =+0.409, the more the BMI increase patient the more increase in the amount of seroma collection in breast post-surgery, as well as Significant statistical correlation between BMI and axilla drain amount with Pearson correlation =+0.309, the more the BMI...
increase patient the more increase in the amount of seroma collection in axilla post-surgery.

DISCUSSION

A seroma is an accumulation of serous fluid that develops following the formation of skin flaps during mastectomy or in the axillary dead space in the post-operative period. The most likely cause for the formation of seroma is the disruption of lymphatic channels in the axilla. However, laboratory studies have shown conflicting evidence, some determining the fluid to be lymph-like in quality and others showing an inflammatory exudate.

The problem of seroma formation is multifactorial; the patients’ age is one of the factors that showed negative correlation in our study, as the age of the patient was not correlated to the amount of fluid accumulated. This was similar to the study presented by Ernest et al. in which they also suggested there was no relationship between the age of the patient and the development of seroma. In other study by Tejler and Aspegren a direct correlation has been shown to exist between the age of the patient and the development of seroma.

Also, the patients’ BMI was statistically correlated to the seroma formation, the higher the BMI, the more patients showed tendency to seroma formation post-operatively in our setting. Similarly this was also found by other two studies by Kumar et al. and Burak et al.

Selected patients who had other comorbidities were assessed, in our study we included diabetic patients and they showed higher rate of seroma formation as well as surgical site infection in the form of fever and cellulitis of the wound itself, without change in the color of seroma fluid.

Pre-operatively, a group of the patients received neo-adjuvant chemotherapy, those showed higher incidence of seroma formation in our setting. In another study by Forouhi et al. found that neo-adjuvant chemotherapy did not influence seroma formation in a randomized clinical trial comparing neo-adjuvant chemotherapy with immediate surgery.

Other factors were assessed as intra-operative number of positive lymph nodes taken into the specimen and level of axillary dissection. This was not supported by other opinions as Lumachi et al. found the number of lymph nodes of no significant impact on incidence of seroma.

The challenge was to implement a procedure to reduce the rate of seroma without significantly increasing operative time, blood loss, or other morbidity.

Furthermore, some post-operative factors surgical site infection showed positive correlation which needed to be studied further to prove and/or negate causation relation between both factors.

Various studies have attempted to reduce seroma formation in order to improve outcome and reduce morbidity. Techniques that have been advocated over the years include shoulder immobilization, prolonged suction drainage, perioperative tranexamic acid, choice of surgical instrument, and obliteration of dead space.

In our study, we standardized the use of suction drains to all the patients. In another study by Whitfield et al. an illustration of the preference of suction versus siphon drainage after axillary surgery seroma formation and it was found that it was not influenced by the choice of closed suction drainage or passive drainage.

The use of electrocautery was significantly associated with increased seroma formation in an RCT by Porter et al.

Suture flap fixation is a surgical technique for securing flaps to underlying tissues to close the dead space with sutures. Although this technique is not commonly performed, a prospective study by Schuijtvlot et al. has demonstrated that seroma formation is reduced by the use of this technique in patients undergoing BCT without axillary drainage.

Chand et al. suggested that the post-operative fluid collections following mastectomy and axillary clearance arise from disrupted axillary lymphatics to a greater extent than serous fluid formation from mastectomy flaps.

If it is believed that the largest potential dead space is the empty axillary apex after axillary dissection or indeed that seroma formation is contributed significantly to by disruption of axillary lymphatics, it follows that closure of this space may prove useful.

A few studies introduced the concept of axillary padding to reduce drainage volumes after axillary surgery. The axillae were padded with nearby tissue, and outcomes in terms of seroma formation were excellent. However, both main studies carried out a limited axillary dissection, and were carried out on patients undergoing breast conservation.

In our technique we have shown that reliably excluding the axillary fossa from the remainder of the mastectomy wound can considerably reduce post-operative drainage volume in this small group of patients.

Contrary to popular belief, a study has shown that the length of time drains are left in place does not affect seroma rate. Few results have shown consistent benefit.

Drainage volume during the initial 3 or 5 postoperative days (POD), total drainage volume and drainage volume in the 24 h before drain removal were assessed in terms of seroma formation. Among them, a positive association between drainage volume during the initial 3 POD and seroma formation was consistent between two RCTs.

In contrast, evidence was inconclusive for drainage volume in the 24 h before drain removal, total drainage volume during the initial 5 POD or total drainage volume. In this respect, the effect of total drainage volume might be confounded by duration of drainage and vice versa.

In our study, the patients were seen for follow up, the first visit was at the 4th postoperative day where the first evaluation was made. The second visit was at 6th postoperative day where drains are usually removed. Axillary bed drains and mastectomy bed drains were assessed, there was significant statistical difference between the cases and controls regarding drain amounts collected in mastectomy bed drain and axilla drain (p < 0.05) except for mastectomy bed drain on day 4 post-operative where no statistical significance was found.
when comparing drain amount of breast in D4 in both cases and controls (p > 0.05).

Time of initiation of arm movement has also been studied on the basis that chest wall motion and shoulder use create shearing forces that delay flap adherence, and that postoperative arm use acts as a pump forcing lymph into the empty axillary fossa. However, studies have shown no significant difference when delaying rehabilitation, and in fact the consequences of shoulder stiffness can be far greater than that of simple seroma.\textsuperscript{16}

**Summery**

**Conflict of Interest:** No Conflict of Interest

**References**