ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 12, Issue, 01, pp.9718-9722, January, 2020

DOI: https://doi.org/10.24941/ijcr.37840.01.2020

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

SEROMA FORMATION IN HALF V/S FULL VACUUM SUCTION DRAINAGE AFTER MODIFIED RADICAL MASTECTOMY-A HOSPITAL BASED PROSPECTIVE COHORT STUDY

Dr. Syed Ghazanfar Imam[1,*], Dr. Devendra Saini[2], Dr. Rajendra Bagree[3], Dr. Jagram Meena[4] and Dr. Shubhanshu Gaurav[5]

[1]Junior Resident, Department of General Surgery, SMS Medical College, Jaipur - 302004 (Rajasthan)
[2]Assistant Professor, Department of General Surgery, SMS Medical College, Jaipur - 302004 (Rajasthan)
[3]Senior Professor, Department of General Surgery, SMS Medical College, Jaipur - 302004 (Rajasthan)
[4]Assistant Professor, Department of General Surgery, SMS Medical College, Jaipur - 302004 (Rajasthan)
[5]Junior Resident, Department of General Surgery, SMS Medical College, Jaipur - 302004 (Rajasthan)

ARTICLE INFO

Article History:
Received 24th October, 2019
Received in revised form
30th November, 2019
Accepted 19th December, 2019
Published online 30th January, 2020

Key Words:
TNA, SWOT analysis,
EMB factors,
Fishbone Analysis and Performance.

ABSTRACT

Background: Breast cancer is the second most common malignancy in Indian women. Surgery is the mainstay of treatment. Modified radical mastectomy with or without reconstruction or breast preservation in addition to axillary lymph node dissection are common surgical procedures in breast cancer. Surgery of the axilla is associated with numerous complications, including infection, lymphedema of the ipsilateral upper extremity and collection of fluid in surgical site (seroma). Most common complication after breast cancer surgery is seroma. The exact etiology of seroma formation remains controversial. It is an accepted fact that negative suction prevents seroma collection and helps in the adherence of the walls of the axilla thus reducing the dead space and allowing the lymphatics to close. But, High negative suction pressure generated by the drain can maintain lymph drainage by a negative pressure gradient, paradoxically, not allowing the lymphatic channels to close leading to continuous drainage and a higher incidence of seroma formation. In our study, we evaluated two groups of patients, who had, the full and half vacuum suction pressure drains in situ, respectively, for their effect on seroma formation. Methods- The study was conducted in the general surgery / Oncosurgery department of S.M.S. Medical College and attached group of hospitals, Jaipur, from March 2018 to Dec 2019. 40 patients each belonged to the two respective groups that were compared and evaluated for the seroma formation. **Results:** In the present study it was observed that high suction caused prolonged drainage, which can possibly be explained by the hypothesis that high negative suction may not allow, leaking lymphatics to close. Therefore no suction or high suction drainage both may contributed to the same result that is higher incidence of seroma formation and longer hospital stay. **Discussion**: To strike a balance between not having suction at all and having a very high or full negative suction, half negative suction drainage was used in the present study to achieve a shorter hospital stay without any increase in the rate of post-operative seroma formation. But it was not found to effectively reduce the Hospital stay and also did not increase the postoperative morbidity as compared to high (full) negative suction group.

Citation: ***Dr. Syed Ghazanfar Imam, Dr. Devendra Saini, Dr. Rajendra Bagree et al.*** **2020.** "Seroma Formation in Half v/s Full Vacuum Suction Drainage after Modified Radical Mastectomy-A Hospital Based Prospective Cohort Study", *International Journal of Current Research*, 12, (01), 9718-9722.

INTRODUCTION

Breast cancer represents the most frequent cancer entity in western countries and second most common cause of cancer related female deaths (Jemal, 2006). In India, it represents second most common malignancy in women after cancer cervix as per national cancer survey 2006-08 (National Cancer Registry Programme).

Corresponding author: **Dr. Syed Ghazanfar Imam,**
Junior Resident, Department of General Surgery, SMS Medical College, Jaipur - 302004 (Rajasthan).

Although breast cancer can be detected at earlier stages by simple breast examination, in developing countries maximum (>90%) cases are diagnosed in advanced stages i.e. stage IIB, III and stage IV.[4] The standard surgical management of most women with operable breast cancer is resection, depending upon stage of the tumour. In early stage excision of the primary tumour can be done by wide local excision (WLE) and sentinel lymph node biopsy (SLNB) or breast conservation surgery. Mastectomy is indicated for patients who are not candidates for breast-conserving therapy, patients who prefer mastectomy, and for prophylactic purposes to reduce the risk

of breast cancer.Total mastectomy and sentinel lymph node biopsy (SLNB) or axillary lymph node dissection (ALND) is considered to achieve loco-regional control, staging and accurate prognostication. Complications after mastectomy include seroma, wound infection, skin flap necrosis, chest wall pain, phantom breast syndrome, and arm morbidity.Seroma is a collection of serous fluid in the dead space of post-mastectomy skin flap, axilla or breast following modified radical mastectomy (MRM) or breast conserving surgery (BCS) and is the commonest early sequel (Kumar, 1995). However, there is inconsistency in the definition of seroma across published works. This presumed complication, albeit usually of minor consequence, may prolong recovery, length of hospital stay and over stretch health budget. The reported incidence of seroma formation varies widely. There are several factors implicated in seroma formation like the extent of lymph node clearance, number of positive nodes, the use of postoperative radiation and whether intraoperative lymphatic channel ligation was done or not, but opinion differs as to their individual role in its pathogenesis (Akinci, 2009; Kuroi, 2006).

The main pathophysiology of seroma is still poorly understood and remains controversial. The optimal ways to reduce the incidence of seroma formation are unknown. Seromas of the axillary space can lead to significant morbidity and delay in the initiation of adjuvant therapy. Various techniques and their modifications have been practiced and published in literature, but there seems to be no consensus. In our study we have evaluated that whether or not the Half v/s Full Vacuum Suction Drainage, reduces seroma formation in patients undergoing MRM.

MATERIALS AND METHODS

This prospective randomized control study was conducted in the upgraded department of general surgery of SMS Medical College and attached group of Hospital, Jaipur, for duration of June 2018 to December 2019. Eighty FNAC proven cases of locally invasive breast cancer (clinically staged according to the AJCC 7th edition) following complete routine and metabolic work up underwent standard MRM as treatment for ca breast. These Eighty cases were divided into two groups randomly by block randomization based on the type of suction used postoperatively. Group A had full suction and group B used half vacuum suction. [Group A: 100 mm Hg pressure; Group B: 50 mm Hg pressure]. The operative procedure (using standardized technique with electrocautery) was performed by the same surgical team in both groups and other surgical team of department of general surgery and Oncosurgery.

Axillary dissection was done up to level-III in all these cases. Two silicon tube drains (16 Fr) were inserted in all the patients post operatively. Both the drains were connected to a single 600 ml suction bottle (Romovac). In-group A (n = 40), drainage was performed using complete vacuum negative suction (100mm of Hg) and in-group B (n = 40) on first post-operative day using full vacuum negative suction, thereafter with half vacuum suction drainage (50mm of Hg).The mean duration of Hospital stay was 3 days in both group. All Patient Discharged with Drain after patient was trained to monitor 24 hrs Drain output which was then followed by me. The data were collected by pre-structured pre-tested Performa. The total drain output was measured and recorded daily in both the groups; mean drain output of three days were considered for calculation.

Drains were removed when the output was less than 10 ml in 24 hrs. The mean total drain output was measured in each group and compared. The mean hospital stay in both the groups was calculated and compared. The associated morbidity in the form of seroma formation, flap necrosis and wound infection during the postoperative period were recorded and compared in both the groups. Data was analyzed by Microsoft excel and statistical software SPSS. The frequency distribution, figures, proportions, measures of central tendency and appropriate statistical test were done. p-value <0.05 will be considered as significant.

RESULTS

A total of 80 patients were included in the study and were divided into two parallel cohorts. It was observed that 19 (23.75%) of the total had developed seroma after MRM. Most patients that developed seroma belonged to 33-79 years of age, (mean- 60.31±15.23 years). The seroma formation showed positive correlation with tumor size, 8 out of 19 patients who had developed seroma, had tumor size of 5 cms or more (p value- 0.0401) (Table.1). Likewise, coming to the magnitude of surgery and tissue dissection, 13/19(68.42) patients had more than 12 nodes resected during the surgery and showed highly positive association with the post-surgery seroma formation (p value<0.0001) (Figure. 1). Another interesting association was seen with the status of surgical wound infection and skin necrosis which was seen in 4/19 (21.05%) patientsafter the surgery, both the factors showed a highly positive association as a predictive factor for seroma formation (p value -0.0024). The total hospital stay (mean 3.57±0.90 days), did increase in patients with seroma formation, again showing a positive association with p value <0.0002 (Table.2). Additionally, duration for which the drainage was done and total drain output both had a positive association with seroma formation with p value<0.0001.

Seroma formation as a function of “type of suction drain” placed in situ, was assessed in our study. Out of the total of 19 patients that showed seroma formation, 10 (52.63%) had a full suction drain in situ while 9 (47.37%) had half suction drain, the cohort with half suction v/s full suction, did not show any significant association (p value-0.1665) as was also seen with the duration for which the drainage was done in both the cohorts (p value-0.1509), in developing seroma formation. The type of drain showed no statistical significance with other factors like age of patient, number of nodes resected, status of surgical wound or stay of duration in the hospital. However, there was a positive co-relation between the drain output in ml for each type of suction drain, which was an average of 910 ml for half suction and 1056 ml for full suction drain respectively (pvalue< 0.0231) (Table. 3). Type of drain output as a function of positive lymph nodes and tumor size has also shown positive statistical correlation. On the basis of Neo-adjuvant chemotherapy status (NACT), the cohorts were assessed. Number of patients who received with NACT were 35 with Average number of NACT cycles being 4.085±1.57. Of which 23(65.71%) had half suction drain and 12(34.29%) had full suction drain respectively showing a significant statistical correlation (pvalue-0.0137) (Table.4). Drain duration (p value-0.0014) and drain output (0.0031) also had a positive association with NACT, irrespective of the type of suction.Out of the total 35 patients who received NACT, 16 (45.71%), developed seroma showing highly significant statistical association (pvalue<0.0001). 14/35(40%) patients who

Table 1. Tumor size related parameters amongst the two groups

Category	Half suction	Full suction	P value
Tumor Size (in cms)			
5 and above	20 (50%)	11 (27.50%)	0.0401
4 or less	20 (50%)	29 (72.50%)	(Significant)

*-Chi Square test, Chi-Squared -4.213

Table 2. Seroma status and duration of hospital stay

Category	Seroma Present	Seroma Absent	P value
Hospital stay (in days)			
Mean±S.D.	3.57± 0.90	2.73± 0.68	0.0002 (Significant)
Range	2-5	2-5	
Median	3	3	

*-Mann Whitney's U test, U test – 285.5

Table 3. Drain output and seroma status

Category	Half suction	Full suction	P value
Drain output (in ml)			
Mean±	910±	1056.25±	0.0231
S.D.	299.14	351.76	(Significant)
Median	900	1025	

*-Mann Whitney's U test, U – 565

Table 4. Type of suction and status of NACT in the study population

Type of suction	NACT Present	NACT Absent	P value
Half Suction	23 (65.71%)	17 (37.77%)	0.0137
Full Suction	12 (34.29%)	28 (62.23%)	(Significant)
Total	35	45	

*-Chi Square test, Chi Squared - 6.071

Table 5. Comparison of Baseline parameters amongst patients with/without chemotherapy

Category	NACT Present	NACT Absent	P value
Lymph node resected			
Mean±	14.05±	8.51±	<0.0001
S.D.	6.87	4.89	(Significant)
Range	4-26	3-25	
Median	12	7	
Tumor Size			
5 and above	30 (85.71%)	1 (2.22%)	<0.0001
4 or less	5 (14.29%)	44 (97.78%)	(Significant)

Table. 6. Hormone receptor status and seroma patients

Category	Seroma Present	Seroma Absent	P value
ER/PR status			
Positive	10 (52.63%)	54 (88.52%)	0.0007
Negative	9 (47.37%)	7 (11.48%)	(Significant)
HER2Neu status			
Positive	6 (31.57%)	7 (11.48%)	0.0394 (Significant)

received NACT were positive for HER 2Neu (pvalue-0.0066), while there was no relation derived from the patient's ER/PR status. Patient who required NACT had a mean age of 54.82±13.95 years (pvalue-0.0355), had a tumor size of 5cms and more (pvalue<0.0001), and had a mean of 14.05±6.87 (pvalue<0.0001) Lymph nodes resected during surgery (Table 5). Total duration of hospital stay however did not show any significant association in the patients on NACT. Interestingly, the seroma formation did show a positive association in patients with positive ER/PR and HER 2 Neu status with p value of 0.0007 and 0.0394 respectively (Table.6).

The average BMI for patients with seroma was much higher in patients with seroma absent (p<0.0001).

DISCUSSION

The incidence of seroma formation varies quite remarkably from 8-85% , a median rate of 20% often being quoted. Seroma may lead to delayed wound healing and infection. Besides the economic loss due to prolonged hospital stay and delay in rehabilitation (Funnell, 1992). Reasons that may account for the occurrence of seroma include a large operative field, division of lymphatic channels, the loose

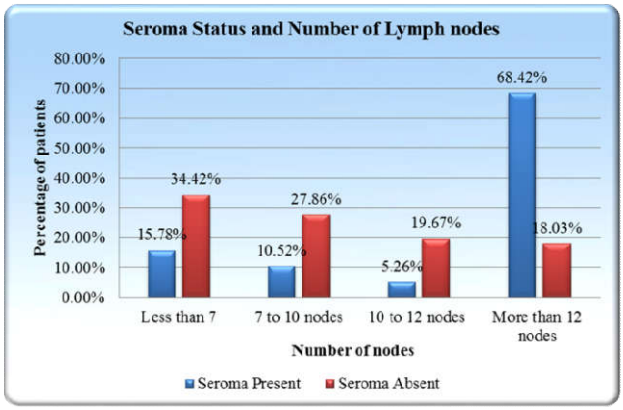

Figure 1. Seroma formation and lymph node resection

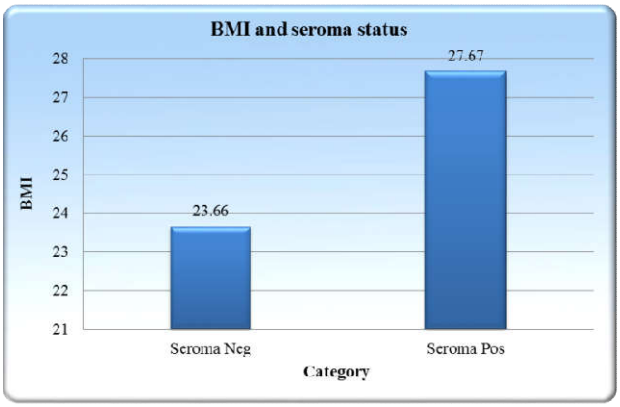

Figure 2. BMI and Seroma status

axillary skin hollow that follows surgical resection and the highly mobile, dependent nature of the area (Hoefer *et al*., 1990). Seroma is often encountered for no obvious reason and without prodromal warning. As for the age co-relation, which is spread across the wide range in our study, the only logical reason could be a decrease in elastic properties of the overlying skin flaps and less rapidity in re-draping to fill up the resultant space from surgical extirpation may be another possible factor. Similar findings have also been reported by Kumar *et al.* (1995) As for the extent of surgery which is directly related to the tumor size and positive axillary lymph nodes, It is logical to suspect that the larger the magnitude of the surgery, particularly when axillary lymphatics are disturbed, the greater the likelihood of seroma formation. This hypothesis is, well supported by the present set of data.

Another inference is that seroma formation is a manifestation of an imbalance between fluid resorption and excessive production and the exposure of raw area to a relatively less pressurized dead as pathophysiological factors besides thermal trauma during surgery, techniques of obliteration of dead space, therefore seem to be advantageous. It has been seen that patients undergoing MRM have a significant increased incidence of seroma formation when compared to those who have breast conservation surgery (Dalberg, 2004). Preservation or removal of the pectoral fascia has no effect on the incidence of seroma. It has also been observed that immediate breast reconstruction following MRM decreases seroma formation when compared to a delayed procedure (Woodworth, 2000), as have been seen in studies by chilson *et al*. (1992) and convey *et al*[12]who showed that employing immediate breast reconstruction with prosthesis to reduce the breast pocket could prove helpful in reducing seroma formation.

Conversely to what we have observed in our study, the number of removed lymph nodes probably does not influence seroma formation (Somers *et al*., 1992). A randomized controlled trial by Purushotham *et al*. (2005) demonstrated that sentinel lymph node biopsy is associated with significantly less seroma formation than that of conventional axillary dissection. Another point of significance is, associated outcomes of prolonged drainage, like risk of infection/tissue necrosis and prolonged hospital stay can further impact treatment by delaying adjuvant therapy. The use of drains after surgery for breast cancer is probably the most investigated and at the same time most controversial of all the techniques aimed at preventing or reducing the incidence of seroma formation. A drain is used routinely after breast cancer surgery with the understanding that it will reduce or prevent seroma accumulation. The influence of negative pressure causing skin flap opposition to the chest wall may facilitate wound healing reduce the incidence of wound infection, wound dehiscence or flap necrosis and prevent seroma formation (Gupta *et al*., 2001). There are however, controversies correlating to the optimal suction pressure, number of drains, duration of drainage or in fact whether the drain should be used at all following breast cancer surgery (Barwell *et al*., 1998).

Petrek *et al*. (1992) randomized 65 patients undergoing axillary dissection or MRM for stage I (or) II carcinoma into one or four suction drains into the axilla and found out, The use of multiple drains in the axilla also conferred no advantage as they did not affect the amount and duration of drainage compared with single drain. Likewise, Dalberg *et al*.[9] in a large multi-centre Swedish randomized trial showed that even the duration of drainage of wound also did not affect the seroma formation. Zavotsky *et al*. (1998) also showed the similar findings that suction drainage had no significant affect on the seroma formation, which is in consensus with our findings. Studies comparing the intensity of negative drain suction have shown mixed results. In a study of 46 patients who underwent mastectomy, randomized between high vacuum drain and low vacuum drain, seroma drainage and postoperative hospital stay was longer in the low vacuum system group than that in the high vacuum system possibly because the high vacuum drain led to more efficient flap approximation to the chest wall (Britton *et al*., 1979). In contrast, van Heurn and Brink (van Heurn, 1995) found that the mean volume evacuated was significantly lower from a low vacuum system, which lead to early drain removal in 76 patients who underwent axillary dissection with breast-conserving surgery. Bonnema *et al*.[21]compared high versus low vacuum drainage, in 141 patients undergoing modified radical mastectomy, lumpectomy with axillary dissection or axillary dissection alone. No significant difference was observed in the volume of axillary fluid produced, drainage duration. Neoadjuvant chemotherapy was developed as a new approach against breast cancer that involves less dissection to achieve better clinical outcomes and patients with metastatic tumors most frequently receive NACT compared to other subgroups. Studies have shown that NACT does convert mastectomy patients to candidates for BCS and reduces the number of dissected lymph nodes (Uyan *et al*., 2016). However, patient preference plays an important role in surgical modality, particularly in the elderly subgroups where MRM is preferred. It has been shown in animal models that NACT administration reduces local inflammatory reaction, which is one of the pathophysiological mechanisms implicated in seroma formation and probably can have a direct effect on the lymphatic circulation by reduction of lymph production

(Bonev *et al*., 2014). Positive association with hormone status, can be explained by the fact that patients had an aggressive tumor and most were the appropriate candidates to receive NACT too, so the extent of tumor cell proliferation in invasive breast carcinomas is known to be regulated by VEGF and are associated with increased expression of ER/PR and HER2/neu. Thus more microvascular density and tumor lympho-angiogenesis could cause more pronounced post-surgical tissue reaction leading to seromas (Choi, 2005).

Conclusion

In a nutshell, the negative suction applied may prevent the lymphatics from closing leading to continuous leakage and discharge and with extent of axillary dissection, more seromas were seen when more lymph nodes were dissected from the axilla. The higher lymph node yield may well be an indirect measure of more extensive dissection performed.The drainage may also reflect the damage to the lymph vessels and therefore the number of lymph nodes dissected may have a bearing on the amount of drainage. In our study also, it was observed that patients with higher lymph node yield had a higher volume and duration of drainage although it was not found to be significantly different in both the groups because they were matched in all respects except the negative suction pressure of the drainage. Similar studies have shown that Half suction drain following axillary dissection can be recommended as an effective approach to reduce the hospital stay and the cost of treatment without adding to the morbidity although it has no effect in reducing the seroma formation.

REFERENCES

Akinci M, Cetin B, Aslan S, Kulacoglu H. 2009. Factors affecting seroma formation after mastectomy with full axillary dissection. ActaChir Belg. 109:481–483.

Barwell J, Campbell I, Watkins RM, Teasdale C. 1997. How long should suction drains stay in after breast surgery with axillary dissection. *Ann R CollSurg Engl.,* 79:435–437.

Bonev V, Evangelista M, Chen JH *et al*., 2014. Long-term follow-up of breast-conserving therapy in patients with inflammatory breast cancer treated with neoadjuvant chemotherapy. *Am Surg*., 80: 940–3.

Bonnema J., van Geel AN., Ligtenstein DA., Schmitz PI., Wiggers T. 1997. A prospective randomized trial of high versus low vacuum drainage after axillary dissection for breast cancer. *Am J Surg*.,173:76–79.

Britton BJ, Gilmore OJ, Lumley JS, Castleden WM. 1979. A comparison between disposable and non-disposable suction drainage units: a report of a controlled trial. *Br J Surg.* , 66:279–280.

Chilson TR, Chan FD, Lonser RR, Wu TM, Aitken DR. 1992. Seroma prevention after modified radical mastectomy. *Am Surg.,* 58:750–754.

Choi W, Lewis M, Lawson D, *et al*., 2005. Angigenesis and lympho angiogenic microvessels density in breast carcinoma: correlation with clinicopathological parameters and VEGF-family gene expression. Mod Pathol18, 143-152.

Coveney EC, O'Dwyer PJ, Geraghty JG, O'Higgins NJ., 1993. Effect of closing dead space on seroma formation after mastectomy – a prospective randomised clinical trial. *Eur J Surg Oncol*., 19:143–146.

Dalberg K, Johansson H, Signomklao T, Rutqvist LE, Bergkvist L, Frisell J, *et al*., 2004. A randomised study of axillary drainage and pectoral fascia preservation after mastectomy for breast cancer. *Eur J Surg Oncol.,* 30:602–609.

Funnell IC, Crowe PJ, Dent DM. 1992. Does surgical experience influence mastectomy complications? *Ann R Coll Surg Engl.,* 74:178-80.

Gupta R, Pate K, Varshney S, Goddard J, Royle GT. 2000. A comparison of 5-day and 8-day drainage following mastectomy and axillary clearance. Eur J SurgOncol. 2001;27:26–30. doi: 10.1053/ejso.1054.

Hoefer RA, DeBois JJ, Ostrow LB, Silver LF. 1990. Wound complications following modified radical mastectomy: An analysis of perioperative factors. *J Am Osteopath Assoc.,* 90:47-53.

Jemal A, Siegel R, Ward E, Murray T, Xu J, Smigal C. *et al*. 2006. Cancer statistics, 2006. *Cancer J Clin.,* 56: 106–30.

Kumar S, Lal B, Misra MC., 1995. Post-mastectomy seroma: a new look into the aetiology of an old problem. J R CollSurg Edinb.40:292–294.

Kuroi K, Shimozuma K, Taguchi T, *et al*., 2006. Evidence-based risk factors for seroma formation in breast surgery. *Jpn J Clin Oncol.*, ,36:197–206. doi: 10.1093/jjco/hyl019.

Meshram II, Hiwarkar PA, Kulkarni PN. 2009. Reproductive risk factors for breast cancer: a case control study online. J Hlth Allied Scs. 8: 5.

National Cancer Registry Programme

Petrek JA, Peters MM, Cirrincione C, Thaler HT. 1992. A prospective randomized trial of single versus multiple drains in the axilla after lymphadenectomy. *Surg Gynecol Obstet.,* 175:405–409.

Purushotham AD., Upponi S., Klevesath MB., Bobrow L., Millar K., Myles JP., *et al*. 2005. Morbodity after sentinel lymph node biopsy in primary breast cancer: results from a randomized controlled trial. *J Clin Oncol.,* 23:4312-4321.

Somers RG, Jablon LK, Kaplan MJ, Sandler GL, Rosenblatt NK., 1992. The use of closed suction drainage after lumpectomy and axillary node dissection for breast cancer. A prospective randomized trial. *Ann Surg*., 215:146–149.

Uyan M, Koca B, Yuruker S, Ozen N. 2016. Effect of neoadjuvant chemotherapy on axillary lymph node positivity and numbers in breast cancer cases. *Asian Pac J Cancer Prev.,* 17: 1181–5.

van Heurn LW, Brink PR., 1995. Prospective randomized trial of high versus low vacuum drainage after axillary lymphadenectomy. *Br J Surg*., 82:931–932.

Woodworth PA, McBoyle MF, Helmer SD, Beamer RL. 2000. Seroma formation after breast cancer surgery: incidence and predicting factors. *Am Surg.,* 66:444–450.

Zavotsky J, Jones RC, Brennan MB, Giuliano AE. 1998. Evaluation of axillary lymphadenectomy without axillary drainage for patients undergoing breast-conserving therapy. *Ann Surg Oncol.,* 5:227–231. doi: 10.1007/ BF02303777.

****