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Original Article

A Prospective Study of the Efficacy of Endofascial Axillary Dissection to Reduce Axillary Seroma Formation

Paul Augustine[1] Srinidhi M.[2] Rexeena Bhargavan[1] Shafeek Shamshudeen[3] Kurien Cherian[1] Preethi Sara George[4]

[1] Division of Surgical Oncology, Regional Cancer Centre, Thiruvananthapuram, Kerala, India
[2] Department of surgical oncology; Mysore medical college and research institute, Mysore, Karnataka, India
[3] Division of Surgical Oncology, MVR Cancer Centre &Research Institute, Calicut, India
[4] Division of Epidemiology and Biostatistics, Regional Cancer Centre, Thiruvananthapuram, Kerala, India

Address for correspondence Srinidhi M., MBBS, MS, MCh, DrNB (Surgical oncology) Assistant professor, Department of surgical oncology, Mysore medical college and research institute, Mysore, Karnataka 570001, India (e-mail: docsrinidhi@gmail.com).

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Abstract

Srinidhi M.

Introduction Seroma formation is a common complication following axillary dissection. The pathogenesis of seroma is poorly understood. Various chemical and mechanical methods have been tried to reduce seroma with varying results. In this study, we look at a novel method of axillary dissection to reduce seroma and its attendant morbidity. The objective of the study is to compare endofascial axillary lymphadenectomy with routine axillary lymphadenectomy regarding axillary drain output following breast conservation surgery.

Methods We did a prospective interventional study of endofascial axillary dissection in patients undergoing breast conservation surgery. Comparison was done with historical controls who underwent breast conservation surgery with routine axillary lymphadenectomy before the study period. All patients were operated by the same surgeon.

Results Breast conservation surgery with endofascial axillary dissection was performed in 36 patients and compared with 36 patients who underwent routine axillary dissection before the study period. The mean total axillary drain output in the endofascial and routine groups were 796.8 and 1,259.3 mL, respectively ($p = 0.001$). The average day of drain removal in the endofascial and routine groups were 10.8 and 14.9 days, respectively ($p = 0.001$). The nodal yield of the endofascial and routine groups were 15.3 and 16.4 nodes, respectively ($p = 0.449$). The duration of surgery of the endofascial and routine groups were 89.3 and 85.1 minutes, respectively ($p = 0.366$).

Conclusion Endofascial axillary dissection significantly reduced the mean total axillary drain output and resulted in early drain removal compared with routine axillary dissection. There were no significant differences in the nodal yield, operative time, seroma aspirations, and wound complications between the endofascial and routine axillary dissection groups.

Keywords
- seroma
- axillary dissection
- breast conservation surgery
- endofascial dissection

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Introduction

Breast cancer is the most common cancer in females worldwide accounting for 24.2% of all the cancers in women based on GLOBOCAN 2018 data. Breast cancer also happens to be the most common cause of cancer-related death in women, accounting for 15% of all cancer-related death in women.[1] In India, breast cancer accounts for 27.7% of all cancers in women and is the leading cancer in women.[2]

Addressing the axilla forms an important component of the locoregional management of carcinoma breast. Seroma formation is a very common sequela following axillary dissection. The pathogenesis of seroma formation is poorly understood and is thought to be multifactorial.[3] Various methods, both chemical and mechanical, have been tried to reduce the seroma formation with varying results.[4] A novel method to reduce axillary seroma is the endofascial axillary dissection which was described by King and Meredith, at The Breast Centre Bowen Hospital, Wellington, New Zealand.[5,6] The aim of our study was to compare the endofascial axillary dissection with the standard method of axillary dissection regarding axillary drain output, nodal harvest, seroma incidence, days taken for drain removal, and complication rates after breast conservation surgery.

Methodology

This is a prospective single institution interventional study performed in a specialist breast cancer unit at a tertiary cancer center. The study was cleared by the Institutional Review Board and ethics committee. The participants were enrolled between July 2018 and June 2019. Preoperative workup included clinical examination, imaging (mammogram and ultrasound of breast), and corecut biopsy from tumor. Patients with histologically proven carcinoma breast undergoing breast conservation surgery were included in the study. Patients who received neoadjuvant chemotherapy, had prior surgery or radiation to the axilla, or had lumpectomy and axillary clearance through a single incision were excluded from the study.

Thirty-six patients underwent endofascial axillary dissection (Group A). An equal number of patients who underwent routine axillary dissection before the period of study were included for comparison as historical controls (Group B). Data regarding these patients were collected using the same proforma from the hospital records as well as by patient interviews. Patients in both the groups were operated by a single surgeon, the first author.

Operative Procedure

The procedure of the endofascial axillary dissection involves identification of the anterior lamina of the clavipectoral fascia at the lateral border of the pectoralis major muscle (►Fig. 1). The clavipectoral fascia is not opened at the lateral margin of the pectoralis major muscle as is practiced in routine axillary dissection. Instead, the full anterior extent of this anterior lamina is delineated, and the incision is placed in a longitudinal direction at its midpoint and the axilla is accessed. The edges of this incised fascia are raised and a loose areolar plane is seen beneath them which is further developed. Medially, the serratus anterior is reached, and the nerve to the serratus anterior is identified and spared. The dissection then proceeds superiorly wherein a deeper layer of the clavipectoral fascia is incised along the lower border of the axillary vein and the nerve to the latissimus dorsi is identified. After identifying the thoracodorsal pedicle and the long thoracic nerve, the interneural tissue is defined,

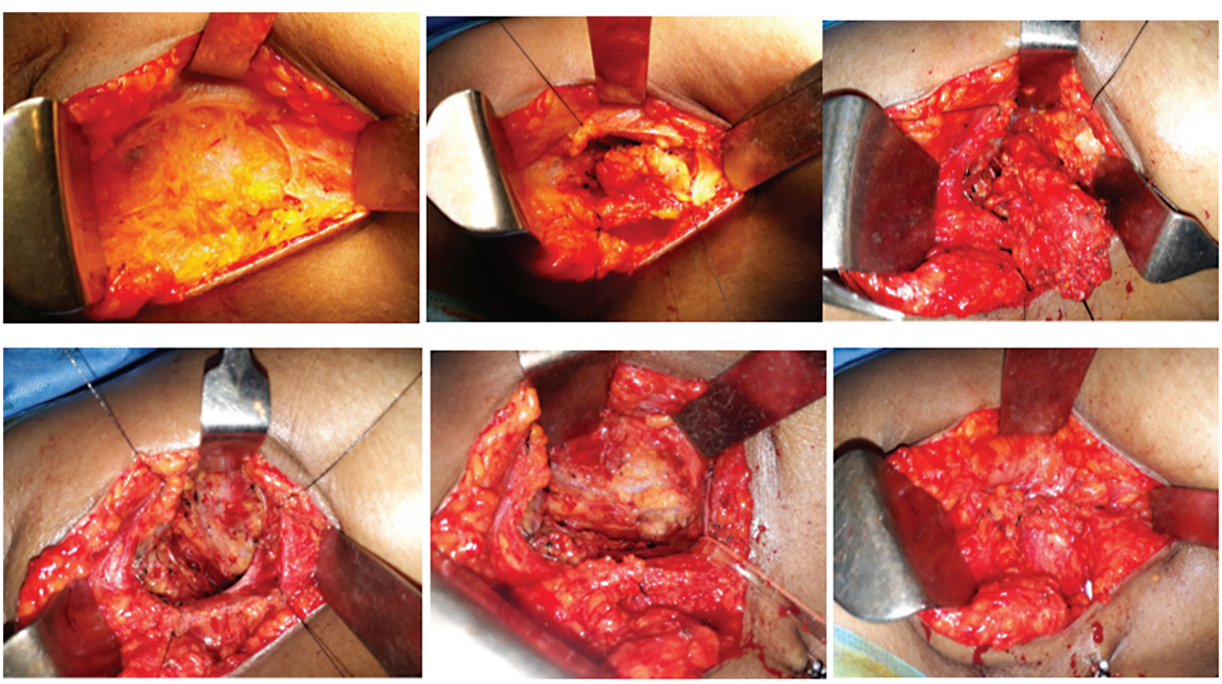

Fig. 1 Operative steps of endofascial axillary dissection.

which is also lined by layers of the clavipectoral fascia. Further axillary dissection proceeds in the routine manner. After completing the axillary dissection, the anterior lamina of the clavipectoral fascia as well as the rest of the axilla is meticulously palpated to look for any remaining nodes. The clavipectoral fascia is then reconstituted with continuous sutures using an absorbable suture material. Suction drains were routinely placed beneath the clavipectoral fascia before closure.

Follow-up and Data Collection

Patients were discharged on the first postoperative day with the drain in situ and advised regarding drain care. The drain output of the patient was charted and periodically reviewed in the outpatient department. The drains were removed once the output of the drains was less than 40 mL for 2 consecutive days provided there was no block in the drain.

Results

The mean age of patients in Group A was 53.9 years, whereas in Group B, it was 50.6 years; 19.4% of patients in Group A and 22.2% of patients in Group B had diabetes mellitus ($p = 1.000$); 41.7% of patients in Group A and 36.1% of patients in Group B had hypertension ($p = 0.808$). Patients in both groups were similarly distributed in body mass index (BMI) categories of <25, 25 to 30, and >30 ($p = 1.000$); 19.4, 58.3, and 22.2% of Group A were in BMI categories of <25, 25 to 30, and >30, whereas it was 16.7, 61.1, and 22.2% for Group B; 25, 61.1, and 13.9% of Group A were stages I, II, III, whereas it was 29.2, 59.7, and 11.1% for Group B ($p = 0.614$); 8.3% of patients in Group A and 13.9% of patients in Group B had extracapsular extension ($p = 0.710$); 13.9% of patients in Group A and 25% of patients in Group B had lymphovascular invasion ($p = 0.234$); 30.6 and 69.4% of patients in Group A had grades II and III disease, whereas it was 47.2 and 52.85% in Group B ($p = 0.147$).

The average duration of surgery was 89.3 minutes in Group A and 85.1 minutes in Group B ($p = 0.366$). The mean number of lymph nodes removed were 15.3 in Group A and 16.4 in Group B ($p = 0.449$); 33.3% of patients in Group A and 44.4% of patients in Group B had positive nodes ($p = 0.334$). The mean total axillary drain output was 796.8 mL in Group A and 1,259.3 mL in Group B ($p = 0.001$); 22% of patients in Group A and none of the patients in Group B had a total drain output of < 500 mL ($p = 0.003$). Drain output was >2,000 mL in none of the Group A patients, whereas 13.9% of Group B patients had total drain output > 2000 ml. (►**Fig. 2**, ►**Table 1**).

The average day of removal of the drain was 10.8 days in Group A and 14.9 days in Group B ($p = 0.001$); 47.2% of the patients in Group A and 5.6% of the patients in Group B had their drains removed in <10 days after surgery ($p = 0.001$) (►**Fig. 3**, ►**Table 2**). The incidence of seroma aspiration (A: $n = 1$; B: $n = 2$), wound infection (A: $n = 1$; B: $n = 2$), wound gaping (A: $n = 0$; B: $n = 1$), and re-exploration (A: $n = 0$; B: $n = 0$) were not different between the groups ($p = 1.000$) (►**Fig. 3**). Age ($p = 0.146$), diabetes ($p = 0.808$), hypertension ($p = 0.933$), BMI ($p = 0.222$), receptor status ($p = 0.119$), number of nodes removed ($p = 0.898$), and nodal positivity ($p = 0.457$) had no impact on the total axillary drain output.

Discussion

The incidence rates of axillary seroma in literature varies from 15 to 90%. Seroma leads to a prolonged discomfort to the patient and also results in infection, pain, and delayed wound healing.[7] A number of risk factors have been proposed as contributory to seroma formation. They include systemic hypertension as well as body weight.[8,9] The role of age, extent of nodal harvest, and nodal positivity remains debated with contrasting results in different reports.[10,11] The T status, diabetes mellitus, size of the breast, smoking, and the use of neoadjuvant chemotherapy were not associated with seroma.[4]

Seroma formation also depends on the type of surgery performed. Women undergoing modified radical mastectomy had more seroma than breast conservation surgery.[12] The number of nodes removed and the nodal status of the patient had no bearing on seroma formation.[13,14] However, women undergoing a sentinel lymph node biopsy had lesser seroma rates than women undergoing an axillary dissection.[15]

The use of suction drains has been associated with lesser seroma.[16] The negative pressure created by the suction drain helps appose the skin flaps, decreases dead space, and reduces seroma.[16] However, the use of high or low vacuum pressure in the drainage system did not influence the seroma formation.[17]

It has been reported that the maximum seroma formation occurs in the first 48 hours after the surgery.[18] The removal of drain at any point of time after this interval has not been shown to significantly determine seroma occurrence.[18–20]

The use of fibrin glue to reduce seroma was thought of due to the low levels of fibrinogen in the seroma fluid. However, there has not been a reduction in seroma with the use of fibrin glue.[21,22] Similarly, the use of bovine thrombin also had no effect on seroma formation.[8] Octreotide was found to significantly reduce seroma formation.[23] Sclerosing agents such as tetracycline, povidone iodine, and ethyl alcohol have been shown to reduce seroma, but their use was associated with infections and pain. However, some studies have shown that tetracycline has not been useful in reduction of seroma.[24,25]

Studies have shown that external compression dressings do not contribute toward reducing the postoperative seroma.[26] Suture fixations such as skin to muscle, skin to fascia, subcutaneous, axillary fascia to muscle have been used. These methods have been associated with a significant reduction in the seroma formation. But they are associated with an increase in the operating time.[27] Different terms such as axillary wadding and axillary padding have been used to describe the suturing of the axillary flaps to the proximate muscles. Tie over sutures have been placed in the axilla to keep the axillary flaps tucked down.[27] All these methods have reported varying results in their attempts at reducing seroma.

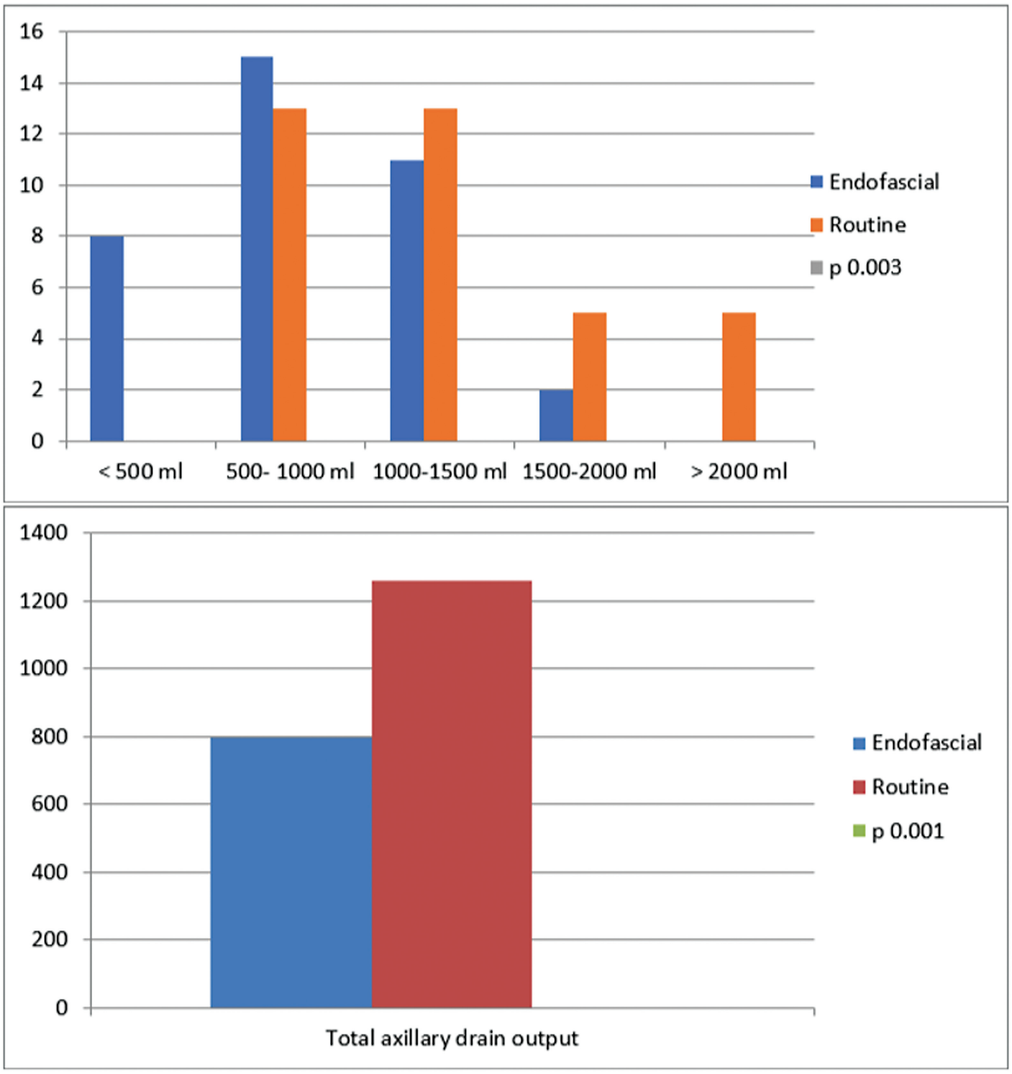

Fig. 2 Upper panel shows distribution of total axillary drain output with number of patients on *Y*-axis and total drain volume on *X*-axis. Lower panel shows the comparison of mean total axillary drain output of both the groups.

Table 1 Comparison of distribution of total axillary drain output

Total drain output		Group A	Group B	Total	*p*-Value
<500	*n*	8	0	8	0.003
	%	22.2%	0%	11.1%	
500–1,000	*n*	15	13	28	
	%	41.7%	36.1%	38.9%	
1,000–1,500	*n*	11	13	24	
	%	30.6%	36.1%	33.3%	
1,500–2,000	*n*	2	5	7	
	%	5.6%	13.9%	9.7%	
>2,000	*n*	0	5	5	
	%	0%	13.9%	6.9%	
Total	*n*	36	36	72	
	%	100%	100%	100%	

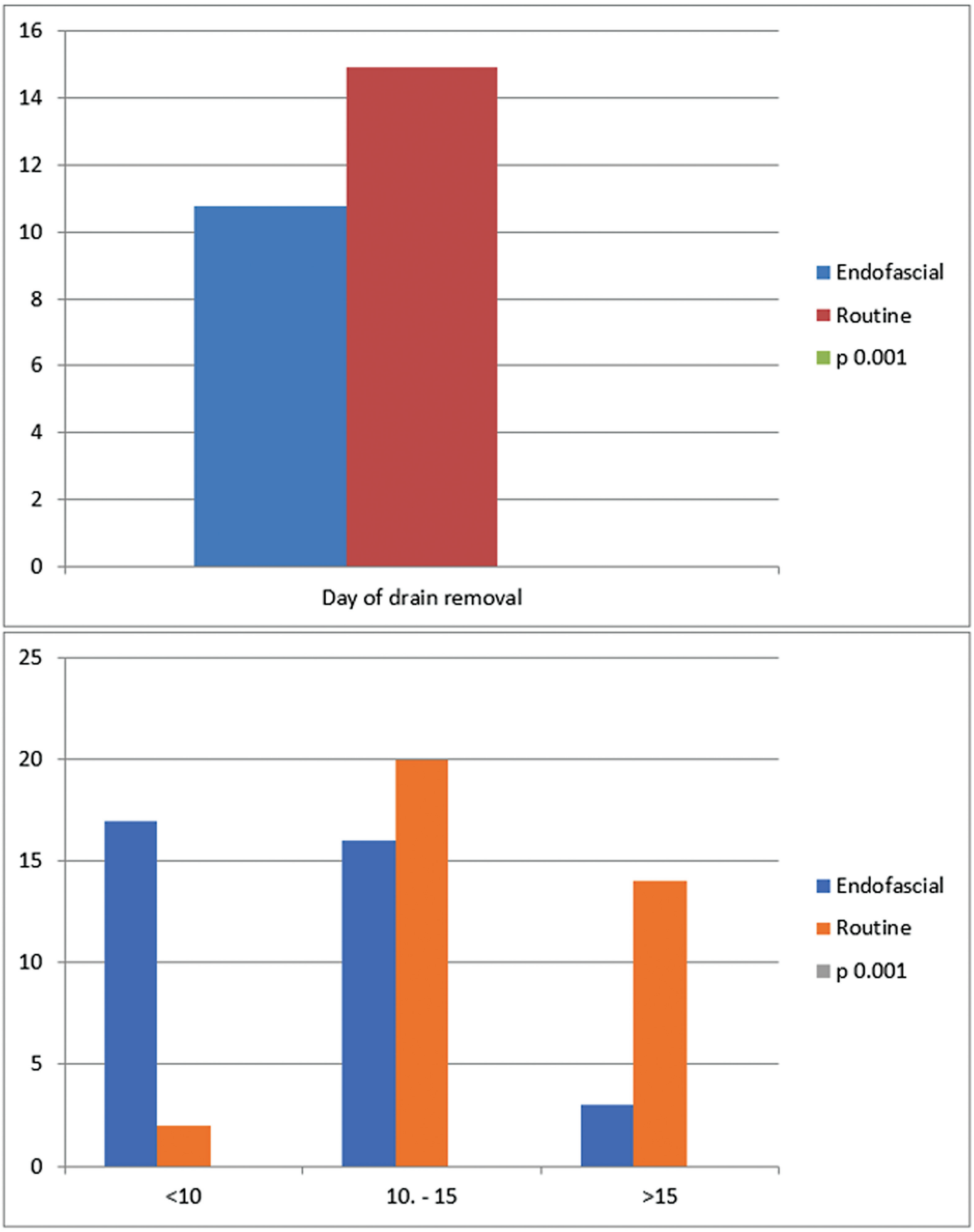

Fig. 3 Day of drain removal. Upper panel shows the comparison of average day of drain removal of both the groups. Lower panel shows the distribution of the day of drain removal with number of patients on *Y*-axis and day of drain removal on *X*-axis.

Table 2 Comparison of the distribution of day of drain removal

Day of drain removal		Group A	Group B	Total	*p*-Value
<10	*n*	17	2	19	0.001
	%	47.20%	5.60%	26.40%	
10–15	*n*	16	20	36	
	%	44.40%	55.60%	50%	
>15	*n*	3	14	17	
	%	8.30%	38.90%	23.60%	
Total	*n*	36	36	72	
	%	100%	100%	100%	

The endofascial method does obliterate the dead space in the axilla similar to suture fixation methods discussed earlier. However, along with obliterating the dead space, the endofascial method also restores the normal fascial anatomy of the axilla. By restoring the fascial anatomy of the axilla, the natural pressure gradients prevalent in the axilla might be restored, which might aid in lymphatic flow.[5] This might not only reduce the seroma formation but also lead to a reduced incidence of lymphedema as well.[28]

The endofascial and the routine axillary dissection groups in our study were well matched in terms of patient characteristics. There were no statistically significant differences in terms of age, comorbidities of diabetes and hypertension, and the BMI of the patients. Node-negative early-stage patients did not undergo a sentinel node biopsy as the procedure of sentinel node biopsy was not yet a standard routine practice in our institute at the time when the study was done.

There were no statistically significant differences between the pathologic stage of the disease, grade, hormone receptor and Her2 status, the presence of extracapsular extension, and lymphovascular invasion. There were no significant differences between the two groups of patients in terms of the number of lymph nodes dissected and nodal positivity.

The duration of surgery was slightly increased in the endofascial group, but it was not statistically significant. The mean total axillary drain output was significantly lower in the endofascial group (796.8 mL) as compared with the routine axillary dissection group (1,259.3 mL), with a difference of more than 450 mL between the groups. While there were eight patients in the endofascial group who had a total drain output of less than 500 mL, there were no patients in the routine axillary dissection group in this category. In the total drain output category of more than 2,000 mL, there were five patients in the routine axillary dissection group, whereas no patient in the endofascial group.

The average day of drain removal was significantly lower for the endofascial group (10.8 days) as compared with the routine axillary dissection group (14.9 days), the difference being more than 4 days. While 17 (47.2%) patients in the endofascial group had their drains removed before the 10th postoperative day, there were only 2 (5.6%) patients of routine axillary dissection group in this category. Fourteen (38.9%) patients in the routine axillary dissection group had their drains removed after the 15th postoperative day, whereas only three (8.3%) patients of the endofascial group were in this category.

The incidence of wound infection, wound gaping, and the requirement of seroma aspiration after drain removal was not significantly different between the groups.

The anatomy of the clavipectoral fascia is central to the endofascial method of axillary dissection. It is a complex, multilaminated, three-dimensional structure. King and Meredith described the handling of the clavipectoral fascia during an axillary dissection. Several layers of the clavipectoral fascia have to be divided lateral to the pectoralis minor muscle. The clavipectoral fascia has to be again opened transversely to visualize the axillary vein. Further, another thin layer of the fascia needs to be divided to visualize the thoracodorsal pedicle. The fascia further condenses at the apex of the axilla to form the costoclavicular ligament. Thus, it is the multiple refections and the condensation of the multilaminated clavipectoral fascia which cover and compartmentalize the axilla. The main difference between the reports published by King and Meredith[6] and our study is that while they did not use drains following an endofascial dissection, we routinely placed drains. While we had a comparison group of routine axillary dissection in our study, they did not report any such comparison. Further, in our study, all the cases in both the endofascial and the routine axillary dissection groups were operated by a single surgeon. Hence, comparison was feasible and was not influenced by variation in surgical method/technique.

The average nodal yield reported by King and Meredith was 12 nodes, while we had a mean nodal yield of 15.3 nodes in the endofascial group, which was comparable with the nodal yield in our routine axillary clearance group. Five out of the 64 women (8%) in the results reported by king and Meredith required seroma aspiration. In our study, only 1 patient out of 36 in the endofascial group required an aspiration of seroma (2.7%). However, seroma aspiration rates of our study cannot be compared with that of King and Meredith because we routinely used drains. However, in our study, we have managed to prove that endofascial dissection has significantly lower axillary drain output and earlier drain removal compared with the routine axillary dissection.

Though we have routinely used drains in all our patients in our study, with the adoption of the endofascial method of axillary clearance, we might be able to progress toward a drainless protocol. This was demonstrated in the study by King and Meredith who did not use drains postoperatively after the endofascial method and had acceptable rates of seroma aspiration.[6]

The early drain removal after an endofascial axillary dissection translates into clinical benefits in terms of improved patient convenience, improved local hygiene, reduced postoperative visits for drain care, psychological benefit, and possibly, early initiation of adjuvant therapy. It might also lead to lower drain and seroma-related issues such as pain, infection, and wound complications.

Endofascial axillary dissection is also likely to result in lower rates of arm lymphedema. We intend to look at the lymphedema rates in the two groups after a longer follow-up. Also, longer term oncological results are unlikely to be different in the two groups as the endofascial method does not hinder the performance of axillary dissection, and this also might be evident on longer follow-up.

Our study is limited by the small sample size and also by the fact that all cases were operated by the same surgeon which, though helps in comparison, calls into question the generalizability of the findings.

Conclusion

Endofascial axillary dissection significantly reduced the mean total axillary drain output and resulted in early drain removal compared with routine axillary dissection. Endofascial and routine axillary dissection had an equivalent nodal yield. There was no significant difference in operative time between the endofascial and routine axillary dissection. There were no significant differences in seroma aspirations and wound complications between the endofascial and routine axillary dissections.

Ethical Approval

The Ethical committee approval obtained from Institutional Review Board (IRB no 01/2018/05).

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None.

Conflict of Interest

None declared.

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