Original Research Article

DOI: http://dx.doi.org/10.18203/2349-2902.isj20183855

Effect of exercise on shoulder function and morbidity following mastectomy with axillary dissection in patients with breast cancer: a prospective randomized clinical study

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Received: 22 August 2018 Accepted: 27 August 2018

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ABSTRACT

Background: There are no guidelines for the exercises performed in physical rehabilitation after breast cancer surgery and, specifically, for how to minimize these postoperative complications. Hence this study was conducted to study the effect of exercise intervention on upper extremity range of motion, strength, lymphedema, pain and activities of daily living (ADL).

Methods: A total of 75 patients were included in the study in accordance to inclusion criteria. They were randomized into exercise group (n=38) and no exercise group (n=37). Patients in the exercise group were given a set of 19 active or active assisted range of motion exercises and strengthening exercises with frequent follow up. The other group were did not receive any strict exercise, they were given a few free hand exercise when they had some shoulder complaints based on treating physician discretion. Apart from demographic data other parameters studied were pain, numbness, active shoulder range of motion, muscle strength, lymphedema and ADL. These were evaluated before surgery, 24 hours after drain removal and 3 weeks /6 weeks/ 3 months of post-surgery.

Results: Demographic parameters were comparable between the groups. Pain score, shoulder ROM were better in the exercise group compared to no exercise group and this difference was found to be significant (p < 0.001). More patients in no exercise group experienced numbness. There was no statistically significant difference in the grip strength between the two groups. The incidence of lymphedema was higher in no exercise group compared to exercise group and this was extremely significant. (p < 0.001). Patients in no exercise group had higher disability scores for ADL which was significant compared to exercise group.

Conclusions: Exercise interventions resulted in significantly reduced pain, improved shoulder ROM and lowered ADL impairment. Exercise intervention significantly reduced the incidence of lymphedema, but there was no effect on strength.

Keywords: Axillary lymph node dissection, Carcinoma breast, lymphedema, Physical rehabilitation, Quality of life, Strengthening exercises

INTRODUCTION

Worldwide breast cancer is the most frequent cancer in women and represents the second leading cause of cancer

death. Recent advances in treatment of breast cancer have resulted in improved survival and the focus has now shifted to rehabilitation and improvement in quality of. Treatment very often is in form of surgery which includes axillary lymph node dissection (ALND). ALND may cause severe, long-term morbidity in patients with breast cancer, such as lymphoedema, pain, numbness, loss of strength and impaired range of arm motion. The focus is now on rehabilitation techniques in order to give patients an adequate mental and physical quality of life.¹⁻³

To prevent loss of arm function and achieve a rapid return to an active social life after breast cancer surgery, a progressive rehabilitation program are required to maintain the flexibility and elasticity of the muscles surrounding the shoulder joint on the affected side.^{3,4} Progressive upper extremity exercise plays an important role in the rehabilitation of patients after modified radical mastectomy which have been reported in the literature.⁵⁻⁷ However, variations exist on the approach of rehabilitation (type, duration, frequency, and intensity) and indicators selected to measure the effectiveness. This study was designed to study the effect of post mastectomy exercise on shoulder function and morbidity in patients of breast cancer.

METHODS

This study was carried out in a tertiary care centre for a period of two years. All breast cancer patients undergoing total mastectomy with level II axillary clearance aged between 18 years to 65 years were included in the study. The study was approved by institute ethics committee. Patients with local recurrence, distant metastasis, diabetes, pre-existing joint disorder (Rheumatoid arthritis etc.), previous surgery on the chest wall, shoulder, arm, patients with visual problems and patients with psychiatric problems were excluded from the study. During the study period a total of 80 patients were recruited according to inclusion criteria. Informed consent was obtained from all the participants in the study.

The participants in the study were randomized into two groups by using computer generated numbered sealed envelope technique. One group was the exercise (E) group of total forty patients and the other was the no exercise (NE) or control group which also had forty patients. In the exercise group two patients were lost to follow up and in control group three patients were lost to follow up.

Exercise System

Exercise group were given physiotherapy with a regimen of 19 active or active assisted ranges of motion and strengthening exercises by qualified physiotherapist. They included movements for flexion, extension, abduction, adduction and internal and external rotation of the shoulder, either isolated or combined. All of the movements described were performed 10 times and there was a 60-second interval between exercises.

This exercise was taught to the patients in the preoperative period and they were begun preoperatively at admission till surgery. Following surgery till drain removal patient was encouraged to ambulate early but formal exercise were started only 24 hours after drain removal. They were sent to physiotherapist daily till discharge that again reinforced the exercise given to them post operatively. The close relatives of the patient were actively involved in these sessions. At discharge patients were given a booklet containing the pictorial diagrams of the exercises they were taught. Relatives were asked to ensure continuance of these exercises at home. At every subsequent visit to the hospital which was mostly weekly once or twice, the patients went to the physiotherapist again who reinforced the exercises in these patients. The exercises were continued till the period of study that is 3 months. Seeing the beneficial effect all these patients were asked to continue exercise even after the present study was completed.

The no exercise or control group were just given a physiotherapy reference for upper limb physiotherapy, but there was no active follow up. Patients are usually taught a few free hand exercises and a few non-structured exercise of the shoulder. But there was no defined sequence or number of repetitions. There was no regular stress on these exercises and as and when patient complained of shoulder pain and swelling they were sent to physiotherapist who continued the same line of treatment.



Figure 1: A) Grip strength assessment using grip dynamometer. B) Goniometer used to assess range of motion. C) compare with the contralateral side: restriction of forward flexion in the same patient in the third week grip strength assessment using grip dynamometer. D) restriction of abduction on the mastectomy side in the 3rd week in control group.

Parameters assessed for outcome

Demographic data like age, BMI educational qualification, details of carcinoma breast/chemotherapy drugs. Level of lymph node dissection, day of drain removal and postoperative complications were noted. Pain as currently experienced by the patient was evaluated. It was evaluated using Visual Analogue Scale (VAS) score. Numbness was evaluated subjectively. A blunt 20 g needle was used and dermatome C3 to T6 were examined by standard technique and compared to contralateral non-operated side.



Figure 2: Lymphedema of the upper limb on the mastectomy side. Compare with the contralateral normal side.

Active shoulder range of motions (ROM) was evaluated (forward flexion, abduction, internal rotation and external rotation). The normal ranges were the following for forward flexion (0° to 180°), abduction (0° to 180°), internal rotation (0° to 90°) and external rotation (0° to maximum preoperative Value). The ROM was assessed objectively by using a goniometer (Figure 1).

Muscle strength of three main groups of muscle was evaluated. The groups assessed were shoulder abductors, elbow flexors and grip strength. The first two were assessed subjectively using MRC muscle grading. Grip strength was evaluated using a dynamometer and it was objectively measured. Lymphedema evaluated by two below mentioned methods.

The first method was by measuring the arm circumference, which was measured at two points like

upper arm circumference (10 cm proximal to olecranon) and forearm circumference (15 proximal to processes styloid us ulnae) (Figure 2).

The other method was the measurement of upper limb volume using water displacement method. It was done using a cylinder of 38 cm diameter filled with water and the level was noted. Upper limb was immersed till the 65% mark (The upper limit of measurement, known as the 65% point, was a point marked on the upper arm which is 65% of the distance from the olecranon to the acromion tip) the new level was noted.

The volume of water displaced was calculated using the formula $\pi r^2 h$; where r is the radius of the cylinder and h is the height of water displaced. An increase in circumference of 2 cm compared to pre-operative measurement or an increase of 200ml in the volume or both were considered as criteria to label the patient as suffering from lymphedema. Activities of daily living (ADL) were evaluated using two well-studied and standardized scales which were Shoulder Disability Questionnaire (SDQ) and Groningen Activity Restriction Scale (GARS).

SDQ was a pain related disability questionnaire, which contained 16 items describing common situations that may induce symptoms in patients with shoulder disorders. A Higher score indicated greater disability. GARS consisted of 18 questions regarding ADL and instrumental activities of daily living (IADL). Five response categories are presented. The items referred to what respondents are able to do and not to their actual performance, which is a very important distinction. Higher score indicated greater disability. All the parameters were assessed before surgery, 24 hours after drain removal, three weeks post-surgery, six weeks post-surgery and three months post-surgery.

Statistical analysis

To analyse these parameters appropriate statistical tests were used. All demographic data like age, side, stage, education status, chemotherapy regimen, drain removal, body mass index, and number of lymph node harvested were analysed using students unpaired t test or chi square test. Other continuous variables were analysed using two-way multiple repeat ANOVA testing.

RESULTS

A total of eighty patients were recruited in the study in accordance to the inclusion criteria. These 80 patients were randomized into two groups of forty patients each. One group was the exercise group and the other was no exercise or control group.

Five patients were lost to follow up, two from the control group and three from the no exercise or control group. Therefore, the total number of patients who completed

the whole duration of study was seventy-five (38 in exercise group and 37 in no exercise or control group).

Table 1: Demographic parameters between the study groups.

Demographic parameters		E group (n=38)	NE group (n=37)	p value	
Age (Mean±SD)		51.7±9.9	49±9.7	0.24	
BMI (Mean±SD)		26.97±2.7	26.8 ± 2.7	0.79	
Side of the	Right	20	21	0.72	
tumour (n)	Left	18	16		
Educational status (N (%))	No forma	15	14		
	education	(39.4)	(37.8)	0.77	
	>Primary	11	10		
	education	(28.9)	(27.02)		

Table 2: Malignant parameters between the study groups.

Malignant parameters		E group (n=38)	NE group (n=37)	p value	
	T3N0	1 (2.6)	0 (0)		
Ctore of	T2N2	1 (2.6)	1 (2.7)		
Stage of	T3N1	15 (39.5)	15 (40.5)		
tumour	T3N2	2 (5.3)	3 (8.1)	0.97	
(N (%))	T4N0	8 (21.1)	7 (18.9)		
	T4N1	11 (28.9)	11 (29.7)		
Ch ama ath anany	CAF	27	26		
Chemotherapy status (N)	PA	10	10	0.99	
	FEC	1	1		
Lymph nodes	Total	8.52 ± 2.65	8.45 ± 2.64	0.90	
removed status (Mean±SD)	Positive	2.32±2.1	2.51±2.2	0.69	
Day of drain removal (Mean±SD)		6.07±0.7	6.4±1.5	0.24	

Baseline demography

All the patients had received pre-operative neo adjuvant chemotherapy and underwent total mastectomy with level II axillary dissection. Mean age of patient (51.7 years vs. 49; p= 0.24) between the groups was not significant. The side of tumour was more on the right side compared to left side in both groups. n both groups most of the patients had no formal education; the next largest group was the group of patients who had completed only primary school.

The distribution of patient according to BMI showed that maximum number of patients in both groups was in the overweight BMI range (Table 1).

Baseline tumour status

Most of the patients were in the T3N1 stage in both the groups. CAF chemotherapy was the most common regiment of NACT used in the patients in the present study.

The mean day of drain removal was 6.07 days in exercise group and 6.4 days in no exercise groups. The mean number of lymph nodes harvested between the groups was not significant (8.52 vs. 8.45; p=0.90). The mean numbers of positive nodes were not significant (2.32 vs.2.51; p=0.69) (Table 2).

VAS pain score

There was no significant difference between the two groups pre-operatively and 24 hours after drain removal. The pain scores were higher in the no exercise group compared to exercise group at 3 weeks (5.81vs.7.5; p= 0.001), 6 weeks (4.7 vs.6.3; p=0.001) and three months (2.9 vs. 4.8; p= 0.001) and this difference was significant.

But when pain score was evaluated after the exercise was started the pain score was lower in exercise group compared to no exercise group and this difference was found to be significant (Figure 3).

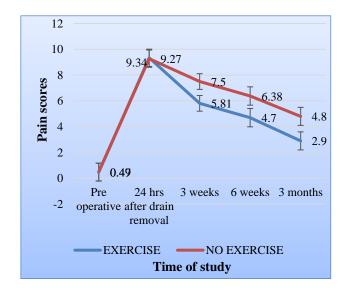


Figure 3: Pain scores between the study groups.

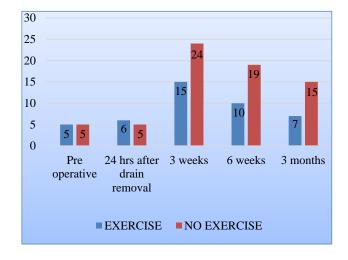


Figure 4: Numbness between the study groups.

Numbness

Maximum patients experienced numbness 3 weeks following surgery, more in no exercise group (15 vs. 24; p > 0.005). At the end of three months more patients in no exercise group experienced numbness. But the difference was not significant (Figure 4).

Flexion ROM

There was no difference between the two groups pre-op and 24 hours after drain removal.

The exercise group had better flexion ROM compared to the no exercise at 3weeks (130 vs. 118; p=0.001), 6weeks (159 vs.134; p=0.001) and three months (170 vs.163; p=0.001). The difference was not significant (Figure 5).

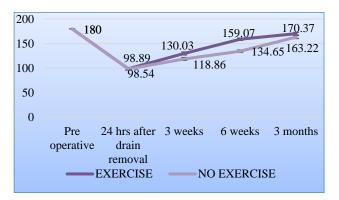


Figure 5: Flexion ROM between the study groups.

Abduction ROM

The two groups had no significant difference at pre-op and 24 hours after drain removal evaluation. But the 3weeks (137 vs. 119; p=0.001), 6weeks (154 vs. 132; p=0.001) and three months (173 vs. 159; p=0.001) evaluation revealed better abduction ROM in exercise group compared to no exercise group which was found to be significant (Figure 6).

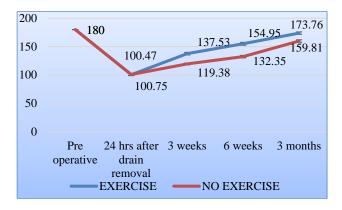


Figure 6: Abduction ROM between the study groups.

Internal rotation ROM

Both groups had matched ROM at pre-op and 24 hours after drain removal time of evaluation. But at 3weeks (48 vs. 42; p=0.001), 6weeks (62 vs. 52; p=0.001) and three months (79 vs. 69; p=0.001) evaluation period showed No exercise group to have significant restriction in ROM which was significant (Figure 7).

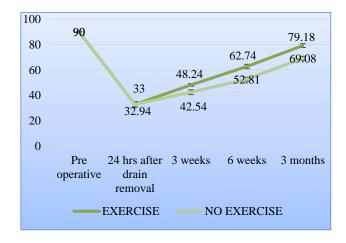


Figure 7: Internal rotation ROM between the study groups.

External rotation ROM

At pre-op and 24 hours after drain removal evaluation for external rotation ROM there was no significant difference between the two groups but at 3weeks (44 vs. 39; p=0.001), 6 weeks (55vs. 50; p=0.001) and three months (71 vs. 61; p=0.001) evaluation showed improved ROM in exercise group and this difference was significant (Figure 8).



Figure 8: External rotation ROM between the study group.

Table 3: Muscle strength between the study groups.

Muscle strength (M	Iean)	Pre-operative	24 hrs after drain removal	3 weeks	6 weeks	3 months
Shoulder	E group	5	3.14	3.30	3.68	4.16
Abduction	NE group	5	3.18	3.29	3.66	4.28
Elbow Flexion	E group	5	3.21	3.47	3.92	4.47
	NE group	5	3.16	3.35	3.68	4.24
Grip	E group	25.16	21.5	23.32	24.45	25.05
	NE group	25.19	21.83	22.86	23.70	24.10

Table 4: Different scores between the study groups.

Different scores	(Mean)	Pre-operative	24 hrs after drain removal	3 weeks	6 weeks	3 months
GARS SCOTES	E group	18.11	68.42	58.69	48.27	39.13
	NE group	18.12	67.35	42.36	33.62	26.02
SDQ scores	E group	0.54	90.12	84.23	80.94	76.25
	NE group	0.16	89.56	65.12	57.45	47.12

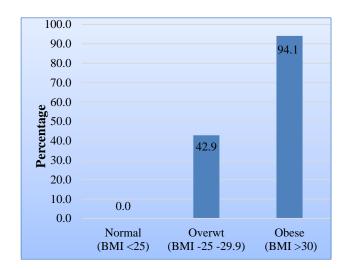


Figure 9: Lymphedema in relation to BMI after 3 months of follow-up between the study groups.

Grip strength

Muscle strength of three groups of muscle was assessed, elbow flexion, shoulder abduction and grip strength. The difference in the strength of these three groups was not found to significant between the two groups (Table 3).

Activities of daily living (ADL)

SDQ and GARS was used to evaluate the effect of exercise on shoulder functioning and ADL. SDQ scores were significantly lower in exercise group compared to no exercise group after exercises were started, meaning lower shoulder dysfunction in exercise group. GARS scores also showed similar trend being lower in exercise group when compared to no exercise group meaning improved ADL in exercise group (Table 4)

Lymphedema

BMI and seroma development were found to be significant (0.005) risk factors for lymphedema development (Figure 9).

Lymphedema was evaluated by circumference and water displacement method. The incidence of early lymphedema (10 vs.23; p=0.005) was significantly higher in no exercise group and this difference was extremely significant. Four patients of these 23 in no exercise group developed frank lymphedema (Figure 10)

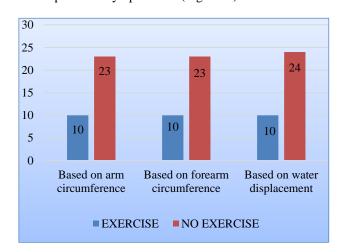


Figure 10: Effect of exercise on development of Lymphoedema between the study groups.

Complication

Local wound complications were recorded, and the incidences of complications were comparable but not significant (p>0.005) in both the groups.

Table 5: Complications between the study groups.

Complications (N (%))	E group (n=38)	NE group (n=37)	p value
Wound infection	7 (18.42%)	8 (21.62%)	
Seroma	10 (26.31%)	9 (24.32)	>0.05
Flap necrosis	6 (15.78%)	5 (13.51%)	
Lymphedema	0	4 (10.81%)	

Seroma was the most common complication noted. Exercise therefore had no adverse effect on complications following surgery (Table 5).

DISCUSSION

Baseline demography

Recent advances in treatment of breast cancer have resulted in improved survival and the focus has now shifted to rehabilitation and improvement in quality of life. Worldwide the mean age of diagnosis is 61 years. In a study done in a tertiary hospital by Parkin et al. the found that the mean age of diagnosis to be 47.39 years. Majority of the ladies in the present study had no formal education, 39.4% in exercise group and 37.8% in no exercise group. The relation between body size and breast cancer risk has been the subject of numerous investigations. Many of these studies have been focused on the association between weight (typically corrected for height) and breast cancer.²

Baseline tumour status

Various studies have shown that the incidence of breast carcinoma is more on the left side in the upper outer. The possible explanations are that the left breast is bulkier, and the upper outer quadrant has a relatively larger volume of breast tissue.³ Drain removal. In a study done by Anderson et al in 63 patients drain was removed on median 4th day following surgery There was no difference in the volume drained in the 24 h preceding drain removal (mean 60 ml).⁴ Seroma formation was associated with a larger total suction drain volume (mean 480 ml). Keeping drains in situ longer did not protect against seroma formation. ⁵

VAS pain scores

The exact cause of this post mastectomy pain is not well explained. Various causes have been hypothesized, like injury or inability to preserve ICBN, brachial plexopathy after radiation, neuroma formation after nerve injury or presence of axillary hematoma.⁶

A few studies have shown the effect of exercise in post mastectomy pain management. In a study done by Shamley et al, they studied the effect of physiotherapy on post mastectomy shoulder function in thirty patients randomized into two groups of fifteen patients each and they found that pain in the shoulder/arm were reduced significantly in treatment group after physiotherapy treatment (p < 0.001) at three months compared with the control group. In the present study also demonstrated the effect of exercise on pain. In the exercise group the pain score was significantly low in the exercise group compared to no exercise group at 3 week, 6 weeks and 3 months of measurement.

Numbness

Numbness is a common problem which patients encounter following surgery. Bendz in his series of 46 patients who underwent MRM found that he could preserve the ICB nerve in 13 patients and 13 so treated were free of throbbing and paraesthesia sensations, while the other 33 had mild to severe complaints. In the present study no conscious effort was made to preserve the ICBN.

There is no study at present to study the effect of exercise on numbness but in the present study the incidence of numbness was highest at 3rd week post op in both the groups but even at 3rd week the incidence was significantly less in the group of patients who had started exercise. Even though no new patients developed numbness, the number of patients who regained their sensations was higher in exercise group. The possible mechanism is probably nerve regeneration or overlap of nerve supply from the neighboring dermatomes which was probably stimulated more in exercise group.

Shoulder ROM and muscle strength

Vecchia et al. in their study in their study in 60 post mastectomy patients randomized into two groups of thirty patients each found that patients had significant restriction in shoulder ROM of flexion, external rotation and abduction. This restriction decreased in the exercise group and the difference at the end of 6 weeks was significant. In the present study too exercise intervention was found to affect shoulder ROM in patients which was significant compared to no exercise group.

Grip strength

Barwell et al. in a study found that in a group of 126 patients who had under gone complete axillary dissection found that incidence of weakness measured by hand grip strength was 25% at the end of first year. They followed up the patients for a period of 4 years and they found that the mean incidence remained the same, around 27%. ¹⁰

Lauridsen et al in their study comparing home-based exercise with usual care in a group of 27 patients found that there were no statistical differences in shoulder strength between groups over time. But external rotation (p=0.036) and grip strength (p=0.001) significantly increased in both groups during the intervention period but there were no interaction effects.¹¹

Lymphedema

Breast cancer related lymphedema is a chronic condition that diminishes quality of life. The incidence of lymphedema following MRM incidence varied from 6.6% to 30.9 %. 12 In the present study the incidence of lymphedema was 45.33% at 3 months post op. Definition of lymphedema in the present study was either increase in arm or forearm circumference by 2 cm or more or a volume displacement of 200 ml or more measured by water displacement method. There is no standardized method of lymphedema assessment and the methods vary studies. 13,14 different The above-mentioned measurements were adopted in the present study as they are most widely used values to define lymphedema

Ferlay et al. in their study of 126 patients used a volume displacement of 200 ml or more to define lymphedema; they found the incidence of lymphedema to be 10 %.13 In the present study both methods of assessment were used to determine lymphedema. However, at the 24 h follow up the volume increases had been reversed, with both phases demonstrating a volume reduction of 15 ml (0.7–1.0%) at this time point.

Activities of daily living (ADL)

SDQ questionnaire was used to assess the shoulder dysfunction in patients following mastectomy. GARS scores were used to evaluate the effect of exercise on activities of Daily living in patients who had undergone MRM.

Low scores were suggesting that exercise interventions resulted in decreased shoulder dysfunction. These questionnaires have been used only recently in breast cancer studies to see the effect of SLNB VS ALND.¹⁵

Complications

Main three early complications seen in the present study were wound infection, seroma, and flap necrosis. Seroma in the present study was the most common complication. It usually presented 7 to 9 days following mastectomy, mostly seen 24-36 hours after drain removal. It was managed conservatively by repeated aspiration and compression bandage. Exercise therefore had no adverse effect on complications following surgery.

Limitations

The Duration of study was for three months. This was to ensure proper compliance of the patients for the duration of study. Longer studies are needed to address the chronic problems following mastectomy. Compliance of patients to the exercise regimen at home was based on the information given by the attendants. No objective measure of compliance was done. Muscle strength was assessed clinically. This was done as kiesthesiometer was not available in the Institute.

CONCLUSION

Exercise intervention in post mastectomy patients improves upper extremity range of motion, reduces incidence of lymphedema and reduces pain. However, there was no significant effect on the improvement of muscle strength. Exercise interventions were also found to improve shoulder function and upper extremity activities of daily living (ADL).

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Das SAP, Sureshkumar S, Vijayakumar C, Kate V, Srinivasan K. Effect of exercise on shoulder function and morbidity following mastectomy with axillary dissection in patients with breast cancer: a prospective randomized clinical study. Int Surg J 2018;5:3217-25.