

EVALUATION OF ROLE OF INTERMITTENT PNEUMATIC COMPRESSION PUMP IN POST MODIFIED RADICAL MASTECTOMY SEROMA

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ABSTRACT

Background: To investigate efficacy of the intermittent pneumatic pump in preventing seroma formation. To determine the reduction in infection rate, fluid collection in drain and duration of hospital stay. **Materials and Methods:** It is a prospective study conducted in a tertiary care hospital for a period of 2 years. 40 patients who underwent modified radical mastectomy were enrolled post operatively. Participants received intermittent pneumatic compression using the device kyosungmed lymphra which is a sequential air compression device with pressure range 30 mm hg to 250 mm hg. The IPC device was applied to the affected limb for 20 minutes for 5 sittings. The outcome was assessed in terms of drain volume and mid arm circumference on days 1, 3, 5, 7 and 9 post operatively. **Result:** The mean age of our study population is 59.7 years, Majority of the study population belonged to ≥ 65 years of age. The mean duration of hospital stay among study participants is 8.2. In our study over a period (day 1,3,5,7 and 9) the mid arm circumference and drain volume among patients decreased significantly with p value <0.05 . This reduction in MAC and drain volume resulted in no seroma formation or infection. **Conclusion:** The study shows that IPC has benefits in preventing the seroma formation post mastectomy. However, the limitation of study is that this is an observational study without control group. Hence further studies like randomized control trials are needed to evaluate the efficacy of IPC in preventing seroma formation.

INTRODUCTION

Mastectomy is indicated for both invasive and non-invasive breast cancers. Modified radical mastectomy (MRM) is defined as a surgery of complete breast removal, with axillary lymphatics, the tumor, overlying skin. Better cosmetic appeal is achieved by preserving pectoralis major muscle.^[1] The most common complications following modified radical mastectomy include seroma, wound infection, wound necrosis, hematoma and lymphedema.

Seroma is the most common complication associated with MRM. The reported incidence of seroma formation varies widely between 15 and 18%. 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.^[2]

The pathogenesis of seroma is not yet fully understood. Seroma is formed by acute inflammatory exudates in response to surgical trauma and acute phase of wound healing.^[3] 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 Seroma accumulation elevates the flaps from the chest wall and axilla thereby hampering their adherence to the tissue bed. It thus can lead to significant morbidity such as wound hematoma, delayed wound healing, wound infection, flap necrosis, wound dehiscence, prolonged hospitalization, delayed recovery and initiation of adjuvant therapy.^[3]

There are several techniques in practice that have been reported to prevent or reduce seroma formation, but no single method has been shown to be consistently and reliably effective. These include surgical techniques, use of sealants, sclerotherapy, compression dressing, use of drains, shoulder exercise (delayed vs early) and the role of Octreotide.^[4]

Intermittent Pneumatic Compression (IPC) therapy is an effective modality to reduce the volume of the lymphedematous limbs.^[5] The sudden application of a uniform external pressure The circumferential

compression of the transmits pressure to the subcutaneous tissues and the muscle groups. Compression increases the interstitial pressure in the extracellular space. When the interstitial pressure is greater than the hydrostatic pressure within the vessels, third spaced fluids are forced back into circulation. This phenomenon effectively decreases the cross-sectional area the extremity and decreases the tensile stretch, The decreased surface tension may provide improved transcutaneous oxygenation and clearance of metabolic toxins.^[6-9]

As a means of using compression therapy for reducing seroma formation following modified radical mastectomy the intermittent pneumatic compression therapy can be applied. There is no existing literature about the role of intermittent pneumatic compression therapy for preventing or reducing seroma formation. But existing evidence shows that intermittent pneumatic therapy is highly effective for reducing lymphedema in post mastectomy patients. Prevention of seroma formation can help in reducing lymphedema incidence. This study aims to understand the efficacy of IPC in preventing seroma formation following modified radical mastectomy.^[10-12]

Aims and objectives

Aim of the study:

- To investigate efficacy of the intermittent pneumatic pump in preventing seroma formation
- To determine the reduction in infection rate, fluid collection in drain and duration of hospital stay

MATERIALS AND METHODS

Study Design: This study is a prospective observational study to evaluate the efficacy of intermittent pneumatic compression (IPC) in managing post-modified radical mastectomy (MRM) lymphedema.

Study setting: The study is conducted at Dharmapuri Medical College

Study Period: 18 months

Study Population: The study included female patients diagnosed with breast cancer following modified radical mastectomy with primary closure. Participants were recruited from the outpatient and inpatient department of surgery in Dharmapuri Medical College.

Inclusion Criteria

- Female patients aged 18-70 years.

- Willing to provide informed consent and comply with study procedures.

Exclusion Criteria:

- Patients with secondary or delayed closure and wound gaping
- Pre-existing lymphedema prior to MRM.
- Presence of severe cardiovascular or respiratory conditions.
- Current infection or skin conditions preventing the use of IPC or compression bandages.
- Pregnant or breastfeeding women.

Sample Size: The final sample size is 49 which is rounded off to 50.

Intervention: Participants received intermittent pneumatic compression using the device kyosungmed lympho which is a sequential air compression device with pressure range 30 mm hg to 250 mm hg. The IPC device was applied to the affected limb for 20 minutes for 5 sittings.

Primary Outcome:

- Reduction in drain volume indicating prevention of seroma formation

Secondary Outcomes

1. Circumference Measurements of mid arm taken on day 1, 3, 5, 7 and 9 on the affected limb using a measuring tape.

2. Shoulder Range of Motion (ROM): Assessed clinically

Data Collection: Baseline Data: Demographic information, medical history, details of cancer treatment, duration of surgery, BMI. Follow-Up Data: Measurements of mid arm circumference, drain volume at days 1,3,5,7 and 9 and observation of range of movements, infection rate and seroma formation.

Statistical Analysis

Data is analyzed using SPSS software. Descriptive statistics is used to summarize the demographic and clinical characteristics of the study population. Independent t-tests or Mann-Whitney U tests is used to compare continuous variables between groups, while chi-square tests are used to compare categorical variables. Repeated measures ANOVA is used to assess changes in outcomes over time within and between groups. A p-value <0.05 is considered statistically significant.

RESULTS

The study included all the participants who consented to receive the IPC intervention post modified radical mastectomy.

I. Basic characteristics of study population:

Table 1: Age distribution, Occupation, side of surgery, Marital status, socio economic status and BMI of study population

Age Group			Occupation		
	Number	Percentage (%)		Number	Percentage (%)
35-45 years	6	12%	Government worker	1	2%
46-55 years	11	22%	Housewife	39	78%
55-64 years	12	24%	Laborer	8	16%
>=65	21	42%	Private concern	2	4%

Total	50	100%	Total	50	100.0
Side of surgery			Marital status		
	Number	Percentage (%)		Number	Percentage (%)
Right	28	56%	Married	40	80%
Left	22	48%	Widowed	10	20%
Total	50	100.0	Total	50	100.0
Socioeconomic status			BMI		
	Number	Percentage (%)		Number	Percentage (%)
Lower	27	54%	Below 18.5 (Underweight)	1	2%
Lower middle	19	38%	18.5 – 24.9 (Normal)	14	28%
Middle	4	8%	25 – 29.9 (Overweight)	28	56%
Total	50	100.0	>=30 (Obese)	2	14%
			Total	50	100%

Majority of the study population belonged to >=65 years of age which is almost half (42%) of the population. This is followed by 55-64 years of age, 46-54 years of age and 35-45 years of age which formed 24%, 22% and 12% respectively of the study population. The mean age is 59.7 and standard deviation is 11.02 the age distribution ranged between 38 and 75 years.

The majority (56%) of study participants had right side breast carcinoma and 48% had left side.

The majority (80%) of study participants are married and 20% are widowed.

The majority (78%) of study participants are Housewife, 16% are laborers, 4% work in private and 2% work in government sector.

The majority (54%) of study participants belong to lower class, 38% belong to lower middle and 8% belong to middle class. Majority of the study population belonged Overweight which is almost half (56%) of the population. This is followed by normal weight, Obese and underweight which formed 28%, 14% and 2% respectively of the study population. The mean BMI is 26.5 and standard deviation is 3.7, the BMI distribution ranged between 17.85 and 36.

Table 2: Height and weight, Vital parameters distribution of study population.

	Mean	Median	Standard deviation	Minimum	Maximum
Height	162.14	162.5	6.305	148	177
Weight	69.7	69	10.332	48	90
Systolic BP	130.76	129.5	15.227	100	178
Diastolic BP	85.6	83	11.334	63	123
Heart rate	90.1	90	18.231	57	100
Systolic BP	130.76	129.5	15.227	100	178

The mean height among study participants is 162.14 and standard deviation is 6.305. Height ranged between 148 cm to 177 cm. The mean weight among study participants is 69.7 and standard deviation is 10.332. weight ranged between 48 cm to 90 cm.

The mean systolic BP among study participants is 130.76 and standard deviation is 15.227. Systolic BP

ranged between 100 to 178. The mean diastolic BP among study participants is 85.6 and standard deviation is 11.33. Diastolic BP ranged between 63 to 123. The mean Heart rate among study participants is 90.1 and standard deviation is 18.231. Heart rate ranged between 57 to 100.

Table 3: Comorbidity distribution among study population

Comorbidity	Number	Percentage (%)
Hypertension	23	46%
Diabetes Mellitus	15	30%
Coronary artery disease	5	10%

The leading comorbidity is hypertension which is 46% followed by diabetes mellitus which is 30% and Coronary artery disease is 10%.

II. Various outcome parameters of study population

Table 4: Duration of hospital stay among study population

	Mean	Median	Standard deviation	Minimum	Maximum
Duration of hospital stay	8.2	7	4.185	3	18

The mean duration of hospital stay among study participants is 8.2 and standard deviation is 4.185.

The duration of hospital stay ranged between 3 to 18 days.

Analysing the mid arm circumference and drain volume over a period.

Table 5: Trend of mean mid arm circumference AND Drain volume over a period

DAY		Mean	Standard deviation	Standard error	95% Confidence interval	
					Lower	Upper
Day 1	MAC	38.12	2.44	.343	37.432	38.808
	DRAIN VOLUME	242.6	6.6	.939	240.712	244.488
Day 3	MAC	37.36	1.5	.220	36.918	37.802
	DRAIN VOLUME	209.8	7.6	1.088	207.614	211.986
Day 5	MAC	36.44	1.8	.264	35.909	36.971
	DRAIN VOLUME	200.2	16.9	2.277	195.625	204.775
Day 7	MAC	36.18	1.9	.267	35.644	36.716
	DRAIN VOLUME	106	9.8	1.400	103.187	108.813
Day 9	MAC	36.08	1.8	.258	35.562	36.598
	DRAIN VOLUME	70.6	10.0	1.426	67.734	73.466

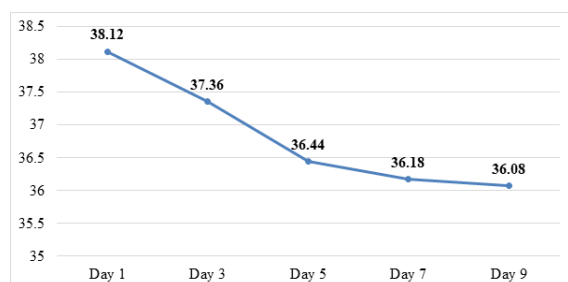


Figure 1: Trend of mean mid arm circumference over a period

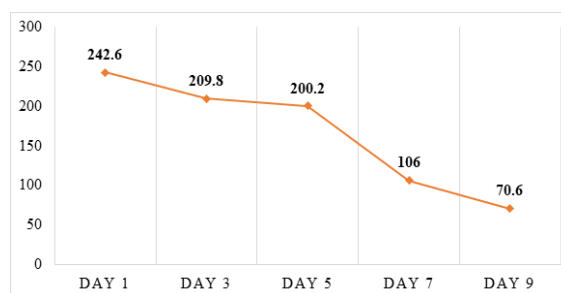


Figure 2: ?

Table 6: Repeated measures ANOVA to find effect of time on mid arm circumference and Drain volume

	Mauchlys statistic	P value for mauchly's statistic	F statistic from repeated measures ANOVA	P values of repeated measures ANOVA
Effect of time for mid arm circumference	0.721	0.071	9.995	<0.001
Effect of time for drain volume	0.311	<0.001	2276.578	<0.001

To check whether over a period there was a significant difference in mid arm circumference, that is whether time had any effect on change in mid arm circumference, test of repeated measures ANOVA is used. In this test sphericity is assumed and it is tested using Mauchlys test. Since mauchlys p value is not significant, the sphericity is followed, and F statistic is statistically significant with P value <0.001 which shows that over a period of time the mid arm

circumference among patients changes significantly however between which days there is significant difference in MAC is summarized in following table. For Drain volume Since mauchlys p value is significant, the sphericity is not followed. Greenhouse-Geisser is used and F statistic is statistically significant with P value <0.001 which shows that over a period of time the drain volume among patients changes significantly.

Table 7: Comparison of mid arm circumference and Drain volume between different days

Time Comparison		Mid Arm Circumference		Drain Volume	
		Mean Difference	P Value	Mean Difference	P Value
Day 1	Day 3	.760	1.000	32.800*	.000
	Day 5	1.680*	.006	42.400*	.000
	Day 7	1.940*	.000	136.600*	.000
	Day 9	2.040*	.000	172.000*	.000
Day 3	Day 1	-.760	1.000	-32.800*	.000
	Day 5	.920	.098	9.600*	.004
	Day 7	1.180*	.024	103.800*	.000
	Day 9	1.280*	.005	139.200*	.000
Day 5	Day 1	-1.680*	.006	-42.400*	.000
	Day 3	-.920	.098	-9.600*	.004
	Day 7	.260	1.000	94.200*	.000
	Day 9	.360	1.000	129.600*	.000
Day 7	Day 1	-1.940*	.000	-136.600*	.000
	Day 3	-1.180*	.024	-103.800*	.000
	Day 5	-.260	1.000	-94.200*	.000
	Day 9	.100	1.000	35.400*	.000
Day 9	Day 1	-2.040*	.000	-172.000*	.000
	Day 3	-1.280*	.005	-139.200*	.000
	Day 5	-.360	1.000	-129.600*	.000

	Day 7	-.100	1.000	-35.400*	.000
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The mean difference in MAC between Day 1 and Day 5, 7 and 9 are 1.6, 1.9 and 2 respectively. This difference is statistically significant with P value <0.05. The mean difference in MAC between Day 3 and Day 7 and 9 are 1.2, 1.3 respectively this difference is statistically significant with P value <0.05.

The mean difference in drain volume between Day 1 and Day 3 is 32.8 ml, between Day 3 and day 5 is 9.6 ml, between Day 5 and day 7 is 94.2 ml, between Day 7 and day 9 is 35.4 ml. This difference is statistically significant with P value <0.05.

DISCUSSION

The mean age of our study population is 59.7 years, Majority of the study population belonged to ≥ 65 years of age which is almost half (42%) of the population. This is followed by 55-64 years of age, 46-54 years of age and 35-45 years of age which formed 24%, 22% and 12% respectively of the study population. This is little higher than that demonstrated in a study by Upadhyay et al where median age for patients was 49 years (range: 19-91 years), with a clustering of 74.83% of cases between 31 and 60 years of age.²³ Another study by doval et al showed almost similar age distribution, A total of 3453 patients with breast cancer were included in the study. The median age at diagnosis was 53 years (20–89 years).²⁵ The mean age is little higher in our study than that in the study by sandhu et al, majority of the patients (65.8%) were in the age group of 31 - 50 years. The youngest patient was 28 and the oldest was 85 years old. The mean age was 47.39 ± 10.90 years. In our study the leading comorbidity is hypertension which is 46% followed by diabetes mellitus which is 30% and coronary artery disease is 10%. This is similar to a study by nechuta et al where the main comorbidities reported included: hypertension (22.4%), chronic gastritis (14.3%), diabetes mellitus (6.2%), chronic bronchitis/asthma (5.8%), coronary heart disease (5.0%).

In our study over a period the mid arm circumference and drain volume among patients decreased significantly with p value <0.05. The mean difference in MAC between Day 1 and Day 5, 7 and 9 are 1.6, 1.9 and 2 respectively. This difference is statistically significant with P value <0.05. The mean difference in MAC between Day 3 and Day 7 and 9 are 1.2, 1.3 respectively this difference is statistically significant with P value <0.05. The mean difference in drain volume between Day 1 and Day 3 is 32.8 ml, between Day 3 and day 5 is 9.6 ml, between Day 5 and day 7 is 94.2 ml, between Day 7 and day 9 is 35.4 ml. This difference is statistically significant with P value <0.05.

The significant change in mid arm circumference and drain volume in this study indicates that there is no seroma formation during the observation period. And none of the patients experienced infection. This is

similar to other studies where IPC has shown efficacy in reducing lymphedema. In a study by Haghghat et al in-Lymphedema Clinic of the Iranian Center for Breast Cancer in 2008, Participants were randomly divided into two equal groups, with one group receiving daily CDT alone and the other receiving CDT combined with IPC. Three months post-treatment, limb volume reduction was 16.9% for the CDT alone group and 7.5% for the combined CDT and IPC group. This study demonstrated that both CDT alone and in combination with IPC significantly reduced limb volume in patients with post-mastectomy lymphedema.

In a study done by Szolnoky G et al mean reductions in limb volumes for each group at the end of therapy, and at one and two months were 7.93% and 3.06%, 9.02% and 2.9%, and 9.62% and 3.6%, respectively ($p < 0.05$ from baseline for each group and between groups at each measurement). Our study also showed similar results with reduction in mid arm circumference and drain volume which is significant over time.

Our study showed reduction in mid arm circumference and drain volume which is significant over time. This is comparable to other studies like the one by Szuba et al comparing decongestive lymphatic therapy (DLT) alone to DLT combined with intermittent pneumatic compression (IPC). The assessments included water displacement for volume measurement, tissue tonometry for skin elasticity, and goniometry for joint mobility. Results showed that incorporating IPC into standard DLT resulted in a significantly greater mean volume reduction (45.3% vs. 26%; $P < 0.05$).

In our study over a period the mid arm circumference and drain volume among patients decreased significantly with p value <0.05. This is similar to another study by Moattarri et al the mean difference in circumference between the two upper limbs at different phases of study (4 and 8 weeks) decreased significantly at all levels of measurement of the arm, The differences in mean volume between the two upper limbs 4 and 8 weeks after the intervention were smaller than before treatment ($P < 0.05$).

However, there were other studies which has used a comparison group to assess the effectiveness of IPC showed results contrast to our studies and reported that IPC did not add significant benefit to existing treatment. A study by Shao et al which is a systematic review of articles evaluated the effect of IPC for lymphedema the percent of volume reduction was reported in 3 trials. Uzkeser et al reported median arm volume difference for experimental and control groups as 500 ml (range: 60–2,160 ml) and 480 ml (range: 0–1,410 ml), respectively, with a volume at baseline of 840 ml (range: 220–3,460 ml) and 630 ml (range: 180–1,820 ml). There were no significant differences between the 2 groups (p value unavailable). Dini et al stated the number of patients achieving a $\geq 25\%$ volume reduction in the 2 groups

(10 patients versus 8 patients) and found no difference between groups ($p = 0.59$). Johansson et al compared the effects of IPC and DLT and stated a percent reduction of volume of 7% and 15% ($p = 0.36$). From the results above, it was concluded that there was no significant difference in the management of BCRL with or without IPC.

Effect of IPC in preventing Seroma in our study:

Fluid collection following mastectomy can affect a large area of the operation site or be confined to the axillary fossa. The incidence of seromas, ranges from 20% to over 50%, is of greater concern than the actual volume of serum lost and the duration of drainage. Drainage volumes are not always recorded, they can exceed 2 liters, with volumes up to 3.7–5 liters documented. Tadych and Donegan reported drainage volumes up to 3.6 liters, with only 12 out of 48 mastectomy patients draining less than 500 mL. Many patients required multiple aspirations, with drainage continuing for up to 7 months, and more than 30 aspirations over 2–3 months have been reported. In our study due to usage of IPC the drainage volume significantly reduced over time with mean drain volumes 242.6, 209.8, 200.2, 106 And 70.6 ml on day 1, 3, 5, 7 and 9 respectively 27.

This shows that the IPC can reduce the drain volumes and hence reducing the occurrence of seroma, in our study the incidence of seroma is 0% which is less than that expected 20% to 50% as quoted in many studies.

CONCLUSION

- The mean age of our study population is 59.7 years, Majority of the study population belonged to ≥ 65 years of age which is almost half (42%) of the population. Majority of the study population belonged Overweight which is almost half (56%) of the population.
- The leading comorbidity is hypertension which is 46% followed by diabetes mellitus which is 30% and Coronary artery disease is 10%.
- The mean duration of hospital stay among study participants is 8.2 and standard deviation is 4.185. The duration of hospital stay ranged between 3 to 18 days.
- In our study over a period (day 1,3,5,7 and 9) the mid arm circumference and drain volume among patients decreased significantly with p value <0.05 .
- The mean difference in MAC between Day 1 and Day 5, 7 and 9 are 1.6, 1.9 and 2 cm respectively. This difference is statistically significant with P value <0.05 . The mean difference in MAC between Day 3 and Day 7 and 9 are 1.2, 1.3 cm respectively this difference is statistically significant with P value <0.05 .
- The mean difference in drain volume between Day 1 and Day 3 is 32.8 ml, between Day 3 and day 5 is 9.6 ml, between Day 5 and day 7 is 94.2

ml, between Day 7 and day 9 is 35.4 ml. This difference is statistically significant with P value <0.05 .

- This reduction in MAC and drain volume resulted in no seroma formation or infection. This shows that IPC has benefits in preventing the most common complication, seroma formation post mastectomy.
- However, the limitation of study is that this is an observational study without control group. Hence further studies like randomized control trials are needed to evaluate the efficacy of IPC in preventing seroma formation.

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