

Does the morbidity management and disability prevention (MMDP) clinic serve the filarial lymphedema (FLE) patients' preeminent expectation?

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Abstract. Advocacy and training on “Home care” for filarial lymphoedma (FLE) patients are provided through morbidity management and disability prevention (MMDP) clinic commonly known as filariasis clinic and clinical improvement is assessed by follow-up visits. While the physicians aim at reducing the recurrent ADL (coined as ADLA in 1997) episodes, the patients expect reduction in LE volume. The objective of the present study was to know whether the MMDP clinic serves the primary expectation of the FLE patients. LE patients who attended the clinic for at least four follow-up consultations and had LE volume measurements at three points of time during the one year period of observation were considered for analysis. Clinical assessment was done for LE grading and LE volume was measured by water displacement volumetry. Sixty-three patients who fulfilled the follow up criteria were included. It was observed that the median LE volume was 914ml (IQR 269 – 1935) at first visit of the observation period which reduced to 645ml (IQR 215-1666) and 752ml (IQR 215 – 1720) at first and second follow-up visits respectively. Over all, in short span of one year, 21 of the 63 patients (33.3%) who visited MMDP clinic at least four times in a year were benefitted through the MMDP advocacy and the National filariasis control programme need to emphasise on the importance of follow up visits to FLE patients.

INTRODUCTION

Though the causes of lymphedema (LE) of extremities are many, malignancy in developed countries and lymphatic filariasis (LF) in developing countries are the two major causes of the global burden of lymphedema. Being a chronic condition, it leads to prolonged morbidity, disability and affects the quality of life (QoL) in general and in a proportion of the affected individuals it afflicts the activities of daily life (McPherson T, 2003; Harichandrakumar KT *et al.*, 2006; Chandrasena TG *et al.*, 2007). Following Global Program for Elimination of Lymphatic Filariasis

(GPELF), several endemic countries have effectively implemented MDA and 55 of 81 filariasis endemic countries have reached the desired epidemiological targets to stop MDA by 2017. Strategies under Millennium Development Goals (MDGs) and their effective implementation by diseases endemic countries between 2000 and 2015 resulted in 21 per cent drop in people requiring MDA and care for neglected tropical diseases. However, morbidity management and disability prevention addressing about 36 million people suffering from chronic filarial manifestations is a neglected component in almost all endemic countries. True global burden of

lymphoedema (LE) is not known due to paucity of epidemiological studies. It is estimated that 15 million people are affected with LE (World Health Organization, 2013) due to LF in 54 countries and most of the cases are from ten African and South-East Asian countries. For more than two decades, India alone contributes around 45% of the global burden of lymphatic filariasis (World Health Organization, 2013; Michael E *et al.*, 1996). There are several forms of treatments for LE and complex decongestive physical therapy (CDPT) is widely advised in post-surgical LE in developed countries. Ko *et al.* shown that CDPT could reduce LE volume to the extent of 20% to 60% [Ko DS *et al.*, 1998]. However, CDPT requires trained therapist and the characteristics of the patients alter the outcome of the therapy.

In resource poor settings of developing countries where filariasis is the major cause of LE, CDPT is not feasible and the treatment seeking behaviour is completely different from developed countries. In these communities, at least five basic measures of limb washing, foot care, skin care, wound care, suitable foot-wear and treatment of acute episodes must be provided as home-care and in comprehensive treatment facilities the complete package including compressive therapy, manual massage and pressure bandage must be extended. All the endemic countries for filariasis have accepted the strategy of home-care with basic measures and adopted in the National filariasis elimination programme. Morbidity management and disability prevention (MMDP) clinics under primary health care settings provide advocacy and training on home-care exclusively to FLE patients and therefore commonly known as filariasis clinic. Clinical nurses play important role in training on home care including manual massage and support the physicians in clinical assessment on follow-up visits.

Problem statement

Routinely, in MMDP clinic, physician examines the patients on monthly visits for early acute manifestations and clinical nurse manages the LE management. While

the treating physician aims at prevention of acute-dermato-lymphangio-adenitis (ADL) episodes to arrest the LE disease progression, LE patients' preeminent expectation is reduction in LE volume or at minimum, no further increase in LE volume. Less than 10% of FLE patients suffer frequent ADL episodes and in a large proportion of FLE patients ADL is precipitated in unpredicted time. Therefore, when the patients are advised to visit MMDP clinic at periodic intervals and practice home-care with basic measures, it needs to be ensured that the patients will be benefitted clinically, especially reduction in LE volume as it is the main expectation from FLE patients.

Purpose of the study

The main objective of the study was to know whether FLE patients' periodic visits to MMDP clinic serve the primary expectation of the patients in term of reduction in LE volume. The study is expected to give a lead so that the information education and communication (IEC) component in National Filariasis Elimination Programme will incorporate the importance of periodic visits to MMDP clinic and its benefits.

METHODS

Study settings

The study was carried out at MMDP clinic known as filariasis clinic of VCRC, Indian Council of Medical Research (ICMR), Pondicherry, India. MMDP to filarial LE patients is offered as a free service component of the institute for the LE patients residing in the geographical locations where surveys are carried out for various research projects. Patients are advised to visit the clinic for monthly follow-up consultation to ensure that the patients follow home-care procedures. Consultation is given on two days a week for all LE patients and limb measurements are taken once in three months. Patients with symptoms and signs of ADL are assessed by a medical officer to provide conservative treatment.

Study population

Study participants included filarial LE patients attending the outpatient filariasis clinic of VCRC during the period 2014 and 2015. The inclusion criteria for this study were unilateral lymphedema of any grade, ADL episodes not exceeding six and the patients must have visited the filariasis clinic at least four times other than the visits for ADL treatment during this one year. In total 209 patients with lower and upper extremity swelling were examined by the Medical Officer in VCRC-MMDP clinic and 145 cases were clinically diagnosed as filarial lymphoedema. Sixty four Non-LE cases or LE cases associated with chronic venous vascular disease, patients availed pneumatic compression therapies were also excluded. In addition, upper limb LE (2), bilateral lower limb LE (21), those who had more than six episodes of ADL during last one year (9) and those with less than 3 follow up (50) were excluded from the study. Finally, 63 LE cases fulfilling inclusion criteria were considered for analysis.

Clinical assessment

On each visit, medical officer elicited the history between the previous and present visit and examined the patients for LE status and secondary skin changes. For LE grading, WHO described four grading system as briefed here was followed: Grade I - Pitting and completely reversible oedema on elevation of the affected limb; Grade II - Pitting or non-pitting and partially reversible oedema on elevation of the affected limb without any skin changes; Grade III - irreversible oedema with extensive fibrosis indicated by skin thickening; Grade IV – Non pitting oedema with secondary skin changes like hyperkeratosis, nodules, ulcers, warts and mossy foot (Kumaraswami V, 2000). All secondary skin changes observed on each patient were also recorded.

LE Volume assessment: LE volume was calculated by water displacement volumetry as described by Beach RB [Beach RB, 1977]. Volume measurement was done using a steel drum to which a calibrated glass tube was attached. Water was filled in

the drum so that it reaches the 'zero' reading in the calibrated glass tube. Patient was asked to immerse the unaffected leg first and the water level on the calibrated tube was recorded. This procedure was repeated for the affected (LE) leg. The difference between these two reading was referred to the volume chart and the same was recorded.

Reorientation sessions

All these patients have been attending filariasis clinic for maintenance therapy after initial training in LE MMDP procedures and therefore they continue to get the advice to follow meticulously the basic home care procedures that included limb hygiene, foot care, skin care, wound care, nail care, exercise and suitable foot-wear. Physiotherapists attended each patient separately and advised suitable limb exercises as described in MMDP which included toe movements, ankle pumps and knee exercises. They were also advised to report to the clinic within 48 hours of noticing any symptoms of acute episodes. In routine practice, patients are advised to report for monthly follow-up sessions for LE assessment.

Treatment for acute episodes

Medical officer assessed clinically the patients reported symptoms of ADL and treated with first line of antibiotics, reassessed after 48 hours to continue the antibiotics for desirable period and followed up at weekly intervals. Those not responding to first line of antibiotics in one week were reassessed and treated with second line of antibiotics. Patients were released from treatment only after complete resolving of clinical signs of ADL.

Outcome measure

The objective of this study is to know whether the follow-up visits to MMDP clinic meets the LE patients' preeminent expectation of LE volume reduction. Therefore, LE volume was considered as the main outcome measure. Though there are several modern methods proposed by

the researchers for the calculation of LE volume, water displacement method is the most cost-effective and highly reproducible (Brijker F *et al.*, 2000). For each patient, change in absolute limb volume in millilitres was measured at three monthly intervals. However, change at the end of one year of intervention was considered as treatment response. The change in LE volume was informed to the patients in order to motivate them to practice the advocated home-care procedures on regular basis.

Statistical analysis

Simple statistics like mean, standard deviation, median, 1st quartile, 3rd quartile and proportions in percentages were calculated. The normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results revealed that variable LE volume does not follow Normal distribution. To compare LE volume between visits Friedman test for repeated measures was used followed by Bonferroni adjusted Wilcoxon Signed Rank test for multiple pair wise comparisons. To compare proportions of LE grade between visits McNemar-Bowker test for matched pairs was applied. All these analyses were carried out on SPSS software (IBM SPSS Statistics for Windows, Version 22.0. IBM Corp., Armonk, NY. Released during 2013.) and the level $p < 0.05$ was considered as significant ($\alpha = 0.05$).

RESULTS

Study participants

MMDP clinic of VCRC registered 209 filarial LE patients during the year 2014-2015. Among these patients, after exclusions, only 63 patients who attended the clinic for at least four follow-up consultations and LE volume measurements at three points of time during the one year period of observation were considered for analysis.

The characteristics of the participants are given in Table 1. It was observed that over 65% of the patients were females. The mean age was 48.2 (SD \pm 11.6). 57.1% and 42.9% of the patients had right and left lower limb LE respectively. Grade II (38.1%) and Grade III (44.4%) were the predominant manifestations among those attending the MMDP clinic. By recall memory, 34.9% and 17.5% of the patients reported to have suffered with 1 to 3 and 4 to 6 ADL episodes respectively during previous year.

Response to therapy

Though there are several clinical parameters of concerns to the treating physician, almost all the patients expected volume reduction on treatment that too within the short period. The median LE volume based on water displacement method at base line and at two follow-up

Table 1. Characteristics of Study participants at Base line (n = 63)

Characteristics		n (%)
Gender	Male	22 (34.9)
	Female	41 (65.1)
Site of Lymphedema	Right	36 (57.1)
	Left	27 (42.9)
Lymphedema Grade	I	4 (6.3)
	II	24 (38.1)
	III	28 (44.4)
	IV	7 (11.1)
Number of ADL episodes	Nil	30 (47.6)
	1 – 3	22 (34.9)
	4 – 6	11 (17.5)
Age in years (Mean \pm SD)		48.2 \pm 11.6

visits is given in Figure 1. It was observed that the median LE volume was 914ml (IQR 269 – 1935) which reduced to 645ml (IQR 215-1666) and 752ml (IQR 215 – 1720) at first and second follow-up visits respectively.

Improvement in LE status in terms of change to lower grade was also assessed during the follow-up visits. It was observed that 6 of 12 patients (50%) who showed improvement in first follow-up visit showed further improvement in second follow-up visit. Three of the 10 patients (30%) who remained static in first follow-up visit

showed improvement in second follow-up visit. Further, 6 of the 41 patients (14.6%) who worsened in first follow-up visit showed improvement in second follow-up visit (Table 2). Over all, in short span of one year 21 of the 63 patients (33.3%) were benefitted through the MMDP advocacy through the VCRC filariasis clinic.

Improvement in terms of reduction in LE volume was assessed by Post Hoc Test after Friedman’s test and it was observed that the reduction in LE volume was significant in first and second follow-up visits (Figure 2). Pair Wise Comparison of

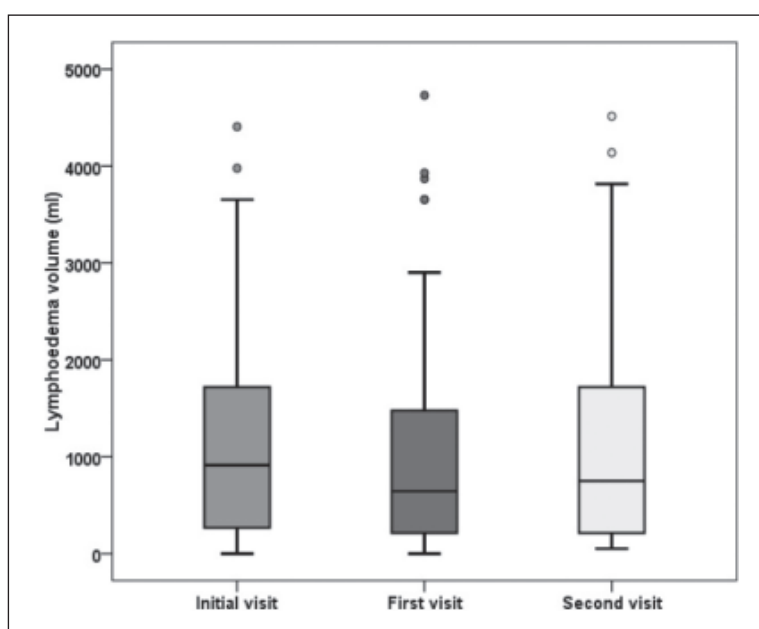


Figure 1. Changes in LE volume at initial visit and at first and second follow-up visits. Bold horizontal line – Median; Box bottom – 1st quartile; Box top – 3rd quartile. The median LE volume is significantly lower in 1st and 2nd follow-up compared to initial visit ($p = <0.001$). The median LE volume in 2nd follow-up visit is not significantly different when compared to 1st follow-up visit.

Table 2. Lymphedema status (Grade) of the study participants at initial and follow-up visits

Lymphedema status	At first follow up			Total N (%)	P-Value
	Improved N (%)	Static N (%)	Worsened N (%)		
Improved	6 (50.0)	3 (30.0)	6 (14.6)	15 (23.8)	0.731
Static	1 (8.3)	4 (40.0)	2 (4.9)	7 (11.1)	
Worsened	5 (41.7)	3 (30.0)	33 (80.5)	41 (65.1)	
Total	12 (100.0)	10 (100.0)	41 (100.0)	63 (100.0)	

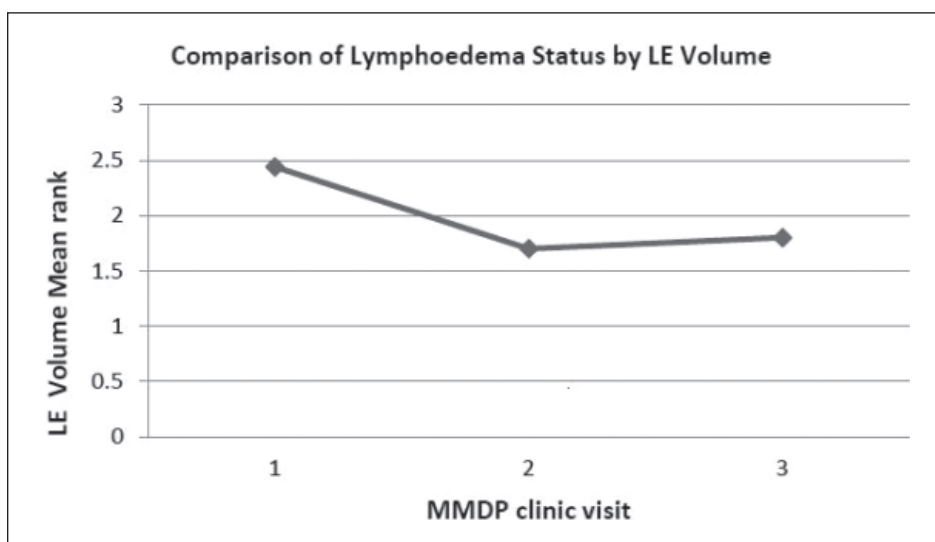


Figure 2. By Post Hoc Test after Friedman's test, the reduction in LE volume in first and second follow-up compared initial visit is significant (Adj. Sig. = 0.000, Adj. Sig. = 0.001) while the reduction in second follow-up compared to first follow-up is not significant (Adj. Sig. = 1.000).

Table 3. Comparison of Lymphoedema Status by changes in Volume

Time Point of Examination	Mean Rank	Friedman Test for Repeated Measures		Post Hoc Test After Friedman Test for Repeated Measures		
Initial visit	2.44	Test Statistics	20.404	LE Volume Comparison	Std. Test Statistics	Adj, Sig.
6 months follow up	1.76	df	2	6 months follow-up and Initial visit	3.786	0.000
12 months follow-up	1.80	P-Value	<0.001	12 months follow-up and Initial visit	3.563	0.001

lymphoedema status by changes in Volume by Post Hoc test after Friedman test for repeated measures showed significant reduction in LE volume at 12 months follow-up (std. test statistics 3.563; adj. sig. 0.001). Indeed, the reduction in LE volume was seen at 6 months follow-up itself and that was sustained at 12 months follow-up also (Table 3).

DISCUSSION

Since disability from existing lymphatic filariasis (LF) will continue to increase for several decades even after successfully

interrupting transmission and raise in cancer survivorship due to availability of various treatment options, the incidence of lymphedema is likely to show an upward trend in developing countries. Home-care that basically promotes limb hygiene has been accepted as the most cost-effective strategy to prevent further progression and disability. To achieve elimination, WHO recommends access to a minimum package of care with 100% geographical coverage for lymphoedema management that includes treatment of painful ADL episodes, preventing ADL and LE progression, access for hydrocele surgery and to destroy remaining parasites from the host through

MDA and individual Mf carrier treatment (WHO 2013). However, there are very scanty reports on the effect of home-care on functional deficit of filarial related LE compared to cancer related LE [Douglass *J et al.*, 2016]. In Odisha, India, in patients practicing limb hygiene, there was a reversal to lower grade at two years follow-up (Budge PJ *et al.*, 2013; Mues KE *et al.*, 2014), whereas in Srilanka Wijesinghe *et al.* observed the grade reversal at one year itself [Wijesinghe RS *et al.*, 2007]. A study in Haiti that included filarial related LE cases in mid stages observed 4% and 17% limb volume reduction respectively through regular limb hygiene at 12 months follow-up. It appears that the evidence for improvement was weak, and therefore insisting on regular therapy in poor resource settings is a challenge.

In poor resource settings, the most suitable approach is the domiciliary limb hygiene coupled with intermittent advocacy in an out-patient clinic, especially for filariasis related LE patients. In the present study, we looked into the outcome in terms of volume reduction among the patients who visited the filariasis clinic at least four times in one year period. By Post Hoc Test after Friedman's test, the reduction in LE volume in first and second follow-up (at one year) compared to initial visit is significant (Adj. Sig. = 0.000, Adj. Sig. = 0.001). Though the reduction in second follow-up compared to first follow-up (six month gap) is not significant (Adj. Sig. = 1.000) there was further volume reduction observed in 50% of the patients.

It has been shown that the reduction in LE volume is remote in late stages of LE irrespective of the cause, modalities of treatment and resource settings (Addiss DG *et al.*, 2010). Therefore, attention must be focused on emphasizing on early intervention to achieve the patients' preeminent expectation of LE volume reduction and alleviate future burden of LE in the communities. Unless the patients' needs are met to their satisfaction, the compliance for follow-up will be poor. Satisfaction survey carried out as a part

of understanding the effectiveness of complete decongestive therapy showed that satisfaction scores reported by upper limb LE patients were lower than those from lower limb LE patients, though there was no significant difference in volume reduction (Barclay J *et al.*, 2006). The authors suggested best suitable consultation approach need to be devised for upper and lower limb LE. In our opinion, reduction in frequency of ADL episodes and reduction in LE volume are inter-related and play major roles in patients' satisfaction and thereby the compliance for limb hygiene at home. These two issues should not be dealt in isolation. Though ADL episodes affect the patients for a brief period of 3-7 days, these episodes have great impact on quality of life (QoL) of the patients (McPherson T, 2003; Suma TK *et al.*, Das LK *et al.*, 2013; Sujin Noh *et al.*, 2015). As per WHO, for any country to claim elimination of filariasis, it is mandatory to have the estimated number of lymphedema and hydrocele patients in each implementation unit, availability of required number of designated treatment facilities and assessment of the quality of services. Sustainable Development Goals (SDGs) proposed in 2012 at the United Nations Conference in Rio de Janeiro seeks elimination of Neglected Tropical Diseases by 2030 under the specific target Universal Health Care (UHC) and therefore, MMDP recommended by WHO gains the major priority in filariasis elimination programme. It is also suggested that MMDP of filariasis eliminations need to be integrated into primary health care system of the country so that the patients will have access to regular follow-up, visits to referral hospitals are avoided so that patients' pocket expenditure is reduced. Results of the present study also show that there is significant reduction in LE volume for the patients who had at least three follow-up visits in a year. Periodic visits under integrated primary health care in addition to home care ensures the added advantages of supervision on home care practices, early detection and treatment of ADL episodes and the reduction in LE volume.

Limitations

Our study has limitations that need to be mentioned. First, the participants are from a single treatment centre drawn on the basis of the consultation visits in one year and therefore cannot be considered fully representative of LE patients. We have also excluded patients with bilateral LE and the results cannot be generalized. Finally, we could not get a matching control group from the same treatment centre as other patients one or more ADL episodes during the period of observation. During ADL, limb volume raises and it takes several weeks to subside in spite clearing the infection. The number of male patients and the grade I and grade IV LE patients were less. Therefore, we could not attempt on the sub-analysis on these parameters including the secondary skin changes.

CONCLUSIONS

Despite these limitations, the results of our study suggest that LE patients' visits at periodic interval are definitely beneficial to the patients in terms of preventing the further progression of oedema as the importance of limb hygiene is reinforced on each visit. In addition, LE patients not following appropriate treatment are more vulnerable for complications leading to costly institutional treatment (Person B *et al.*, 2006) as seen in cancer related LE (Larouche K *et al.*, 2011). On the other hand, as seen in the present study, periodic visits to the PHC ensure reduction in LE volume, the patients' preeminent expectation of MMDP. Therefore, National programme must emphasize follow-up visits, preferably to the PHCs under integrated set-up for the LE management, in addition to the surgical care for hydrocele patients. In our study, we have not assessed the compliance to MMDP home care. Despite that, one third of the patients were benefitted through few follow-up visits to the filariasis clinic. Public health departments in developing countries need to emphasize integration of MMDP in primary health care system for easy access and periodic follow-up for LE management.

Information education and communication (IEC) component in National Filariasis Elimination Programme will have to incorporate the importance of periodic visits to MMDP clinic and their benefits.

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