

Mainstreaming of an Integrative Medicine Protocol for Morbidity Management and Disability Prevention of Lymphatic Filariasis: An opportunity for establishing AYUSH based National Health Programme

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Date of Submission: 27 March 2020 | Date of Acceptance : 8 June 2020

ABSTRACT

Lymphatic Filariasis (LF) is a neglected tropical disease to which all are susceptible but from which the poor in villages become the most disabled. India shares 40% of the global disease burden. The World Health Organization launched in 2000 the Global Alliance for the Elimination of Lymphatic Filariasis (GAELF). Its morbidity control objective currently focusing on the patients of 73 developing nations. However, there is no pan-India public health LF programme to manage lymphoedema. The Institute of Applied Dermatology based in Kasaragod, North Kerala, developed an Integrative Medicine protocol for the treatment of elephantiasis in collaboration with international lymphoedema experts from Europe, Australia and North America. The Bill and Melinda Gates Foundation initiated discussions with Government's health leaders to roll out Integrative Medicine treatment to endemic villages as an ayurveda doctor, and allopathy nurse led programme. Ayush ministry has plans to include it in Health & Wellness Centers under Ayushman Bharat. This paper describes an outline of such possible country-wide implementation.

KEYWORDS: Lymphatic Filariasis, Lymphedema-self-care, Community Health Planning, Community Based Participatory Research, Public Health Practice, Policy Making, Yoga for health

Annals Ayurvedic Med. 2020; 9 (2) 108-115

Introduction

Fundamental policy principles of the National Health policy-2017(NHP) included recognition of medical pluralism to provide access to Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH) care and patient-centred care. By giving thrust to integrating ayurveda and modern science, it emphasises mainstreaming AYUSH as integrated medical care, especially for non-communicable diseases.

Lymphatic Filariasis (LF) is a vector-borne communicable disease transmitted by mosquitoes. It clinically manifests as lymphedema (elephantiasis, known as *Shleepadā* in Sanskrit). The number is not known, but different reports provide with the range of 8-23 million but could greatly

exceed this¹. The IAD has already treated 4000. Microfilaria infection of the blood stream in LF causes larger worms that locate in and cause damage to the long collecting lymphatics with consequent failure of the lymphatic system. Other causes of lymphedema are damage to lymphatics and lymph nodes, either from post malignancy complications such as surgery and radiotherapy of cancer for example the breast or uterus., or by trauma, or entry through the skin by bacteria such as the streptococcus. Recent advice from international geneticists has led to us emphasising more frequently the presence of genetic factors such as primary lymphedema or from the high prevalence in rural villages of cousin marriages. Once lymphedema sets in, it is not reversible, except by a complex morbidity management programme.

GAELF has two main components: interrupting

transmission to the mosquito through mass drug administration (MDA) and Morbidity Management and Disability Prevention (MMDP) of lymphedema¹. MDA interrupts the transmission of LF, by a once-yearly single-dose administration choice of two or three of diethylcarbamazine citrate, albendazole or ivermectin to entire endemic populations for 4 to 6 years. It is made possible mostly through the free drug supply from major pharmaceuticals like Glaxo-Smithkline and E-Merck. Established lymphedema due to a vector-borne communicable disease such as LF, having received adequate rounds of MDA, transforms to a non-communicable status, which unless it receives morbidity management interventions may still have increasing disability and impairment of quality of life.

Morbidity Management and Disability Prevention of LF

GAELF's morbidity control schedule is currently focusing on the patients of 73 countries, wherein LF is endemic. However, there is no consensus on uniformly appropriate treatment options for lymphedema. The benevolent and philanthropic giant the Bill and Melinda Gates Foundation (BMGF) has facilitated MDA in developing countries and is now committed for MMDP through community participation, intersectoral coordination, using appropriate technology of low cost and self-care morbidity management tools for public health and its equitable distribution. Among the treatments available for LF, Integrative Medicine (IM) protocol is the best option for implementation country-wide. The Kerala State Council for Science, Technology and Environment supported the innovation for LF by the Institute of Applied Dermatology (IAD) using IM by a core research grant (previously known as extra-mural research). The initial observation published as a case report in 2004². The International Society of Lymphology gave its president's award for this innovation in 2005. Subsequently, several niche journals acknowledged the effectiveness of treatment³⁻⁵. Because of the global attention received for low-cost IM protocol for LF, the Central Council for Research in Ayurvedic Sciences (CCRAS)

conducted a situation analysis for proof of evidence for the best tool for nationwide MMDP. It funded a community-based study of IM protocol in endemic districts of south India to establish the evidence of its efficacy in village community settings. The study showed that lymphedema self-care IM protocol achieved significant morbidity reduction by improving Quality of Life, lymphedema volume, and recurrent episodes of acute dermato-lymphangio-adenitis (ADLA) due to bacterial entry lesions in 730 LF patients (851 limbs) in endemic villages. CCRAS decided the IM protocol as the current best available tool through a field trial⁶. IM protocol combined the therapies of ayurveda with biomedicine, and yoga delivered simultaneously. IM studies in IAD have shown a high level of safety of ayurveda medicines used in the protocol⁷. The cost-effective IM protocol adopted all the principles of primary health care that is community participation, intersectoral coordination, appropriate technology and equitable distribution. Prof Marlys Witte, department of surgery, University of Arizona College of Medicine, the USA, discussing the new models of lymphedema therapy felt that, although convincing evidence is lacking for the activity of each component an IM protocol of combination therapies, herbal recipes supplemented by manual/manipulative manoeuvres may be as efficacious as single drug therapeutic agent of biomedicine³. She recommended, in her editorial, that the "treatment methods will fit any environment: whether academic medical centre or remote village".

India is slowly reaching the LF elimination endpoint⁸. Apex national bodies are beginning to discuss policy frameworks for MMDP. The Indian Council for Medical Research (ICMR) constituted an expert group (2017) on strengthening MMDP which discussed extended home care using an alternate system of therapy, forming self-help groups at the sub-centre level. In 2018 CCRAS conducted a brainstorming session on AYUSH in public health to work out the strategy and framework for mainstreaming AYUSH in public health aligning with NHP. High officials of the Ministry of AYUSH made site visits to understand the IM protocol for LF⁹. In 2019 National Vector Borne

Disease Control Programme (NVBDP) organised a national symposium with the theme 'United to Eliminate Lymphatic Filariasis'. The BMGF supported the largest conglomeration of Indian experts, bureaucrats and organisations working in the field of LF in New Delhi. The conference displayed and discussed the steps and outcomes of IM treatment protocol. Later the Ministry of AYUSH began consultations with essential stakeholders; NVBDCP, National Centre for Disease Control, and ICMR. Discussions covered technical and operational facilities available in endemic districts, financial resources, tools, strategies and coverage required for the implementation of MMDP.

Scaling Integrative Medicine as a public health programme:

Given the above incremental progress over the past two decades, AYUSH based IM treatment requires a scalable model to help the patient clusters. IM treatment delivered by a team of ayurveda and allopathy doctors, nurses, counsellors, masseurs, yoga therapists. Lack of awareness among populations under risk and affected patients was the most critical barrier for successful implementation of MDA in India. Studies have shown that combining some form of treatment along with education has higher acceptance LF patients to consume drugs of MDA indicating that effective treatment for lymphedema is likely to be accepted in villages¹⁰. Hence patients who have taken treatment previously and experienced the benefits may volunteer to team up with interested media personnel and social activists to take the message to the beneficiaries in endemic villages. It also requires a cluster of institutional support, both Government and willing not for profit, private health care clinics, hospitals and non-governmental development organisations (NGDOs).

The treatment facilities under MMDP should provide the replica of research-based, standard, field-proven IM based treatment protocol. The quality treatment provision is possible by imparting re-orientation training to the AYUSH/Government/not-for-profit hospitals/private doctors and health care workers. Such training should also include field-based experience in newly set up LF care

units in select public health care centres or private hospitals/day-care clinics or as public-private partnership centres as an integrative treatment facility.

Facilities and expertise were built across India that led to a claim by the National Leprosy Eradication Programme (NLEP) of elimination by Multi Drug Therapy (MDT) of another neglected tropical disease. Leprosy care facilities despite the common and persistent disabilities are now sparingly used. Space and personnel available with this previously vertical Government programme could be used for MMDP of LF. The Indian Government and the International and Indian Leprosy Associations partnered with private organisations initiated by Mahatma Gandhi in memory of his wife and by Christian organisations such as The Leprosy Mission, and British Empire Leprosy Relief Association (now known as *Hind Kusht Nivaran Sangh*) are still quite numerous. They are well known for their caring attitude. The World Health Organization's Global Leprosy Strategy includes strengthening Government ownership, coordination and both public and private partnership, and stopping complications and discrimination¹¹. LF endemic regions also suffered from endemicity of leprosy in the past so that the leprosy infrastructure, personnel and services are still available and if permitted could be used for LF-MMDP. LF management requires similar approaches as leprosy, namely disability, ADLA and stigma reduction besides rehabilitation of these large affected populations to economic viability. Utilising the vast expertise of NLEP, still retained with its partner organisations, and training the nurses, community workers, AYUSH doctors and building them as a team to manage LF deformities is an achievable goal discussed by experts¹².

Over the past two decades, the IAD has improved Quality of Life measurement and analysis for LF. As with leprosy, it shows up both the benefits and harm done by isolation and rejection by families or community. This is a common consequence of odour, immobility and recurrent inflammatory episodes. The choice of Leprosy hospitals for lymphatic impairment is as appropriate as using them to manage nerve injury disability from leprosy.

Operational requirements

National Health Policy for MMDP of LF should have multiple components. With vast experience in treating LF patients over the last two decades, the Institute of Applied Dermatology can lead this program as a knowledge provider and technical supporter. The program can be initiated at select endemic areas, possibly in available leprosy facilities or AYUSH sets ups and scaled up later country-wide. The non-residential one-day medical camps could be setting up a screening LF and mobilise complicated and large-sized limbs to the treatment centre. Accredited Social Health Activist and other community health workers will be the key to mobilise patients to the camp. The primary screening of individual patients includes classifying them based on a limb size, bacterial entry lesions and other essential parameters such as quality of life. The camp team should demonstrate easy self-care technique and basic yoga exercises to the patients and bring awareness about the disease and treatment of bacterial entry lesions to prevent the progression of the disease by reducing the risk of recurrent cellulitis¹³. 8-10 camps are required per month in one endemic village to reach a wider patient base. About 30% of patients may need to undergo two weeks of treatment at nearby LF care units. Less complicated patients should receive a medical kit for home-based treatment. The camp should also focus on the patient education session to bring awareness about the disease and self-care and home-based treatment procedures.

The IAD recognises that for several decades lymphedema in India has been managed by surgical teams. Initially, this was debulking, which was expensive and required several weeks in hospital and not without troublesome scarring. Today lymph node transplants and substituting blocked lymphatic vessels with patent vessels can be effective, but for many it is unaffordable and of uncertain durability. Gross enlargement of the genitalia is common due to a special species of filariasis in Orissa and Bihar and is most commonly managed effectively by surgery. The IAD has managed a few genital lymphedema cases without surgery and needs to have the experience of managing many more in order to make the case for successful conservative management¹⁴.

Site selection for LF care units will depend on the collated information from various bodies such as Malaria and Filaria control officers/districts Medical Officers/ National centre for disease control units as well as ASHA^{6,13}. Other operational requirements are locating health infrastructure facility available in selected sites. Moreover, obtaining the government facilities will be a challenge as Indian health services are overstretched. Due to the current COVID 19 pandemic, any proposals to obtain such committed facilities would have to wait for an unspecified time. Existing Leprosy treatment and rehabilitation facilities, including enhancement of well-being (AYUSH Wellness Centres), private clinics/ hospitals of the locality are an essential option that should not be ignored but requires intense supervision. Social distancing has suddenly become a tool of governance similar to isolation used by religious organisations over many centuries and British Empire Governments in the 19th century and requires careful and sympathetic handling as did the best of Leprosy hospitals. A balance of public and private health facility and recruiting willing doctors and health care workers would be an enormous task. For patient mobilisation, a steering committee needs to be formed by including AYUSH doctors to mobilise ASHA, Anganwadi & local community based & friends club workers, other para-medical personal, Junior Public Health Nurses, achieve reference from private health care, involve local bureaucrats and political leaders. They will encourage the patient to reach LF care units, bring awareness about the current medical facility for LF and in India scenario might partially own the media publicity and could be major trouble-shooters if used in a win-win approach¹⁵. Not ignoring all these units and media awareness is an essential societal inclusion strategy for the success of a public health programme of the magnitude required.

Each LF care unit needs to treat per month nearly 150-200 patients with complicated disease and more than 500 of less complicated patients. One Multi-purpose health worker (MPHW-masseur) can treat 5 to 8 patients/day (10-16 massages/day) based on the limb size at local treatment unit. The manual work of ayurvedic oil massage; its duration, techniques by MPHWS depends on IM protocol, duration, variations in limb volume and number

of limbs affected, associated complications, presence of genital oedema, co-morbidities and need for additional skin care requirements. Such prescription requires tweaking in different regions because ayurveda itself is based on individualised treatment and takes into account body constitution, local skin pathology (*sthaneeya vikriti*) and several other clinical parameters for each sub-set of patient groups¹⁶. The MMDP treatment for large limbs requires two weeks of daily attendance to the local unit that operates as a day-care centre. On the 14th day of the treatment, there would be 42 to 112 patients in each centre. So, 12 to 15 MPHW are required for each large service provider unit. Three AYUSH doctors with four nurses are required to manage the estimated patient load and provide treatment/occupational therapy counselling, skincare. The unit also requires yoga therapists to demonstrate and train patients on asanas, movement and gait correction.

The patient load in India demands an NHP mode for MMDP of LF. The initial launch may require external donor support with the private-public partnership. Since LF treatment is a life long initial vertical programme, it should eventually get merged with AYUSH treatment facilities. Pitching in private AYUSH practitioners and linking them for training to regional nodal training centres, Leprosy care facilities or AYUSH facilities would be the first step forward. Care of infection control through the use of antibiotics and management of ADLA and acute exacerbations of associated chronic co-morbidities is an experience to build the confidence of LF care units and specially to recognise clinical indicators to *prevent fatal septicaemia*. Launch of AYUSH mainstreaming of LF IM protocol as NHP could be done in 3-5 centres. Initial planning, preparation and kick-off may require about 8-10 weeks followed by bedside training the healthcare workers for a fellowship certification which automatically achieves patient treatment and capacity building of the health care workers.

Training of Trainers

The training component is crucial in this programme because of the nature of the IM protocol. Training of Trainers (TOT) is the central vertical of this programme to share knowledge and transfer of technology to the local treatment team. It will require two weeks of training to

local doctors/nursing team to familiarise them on IM treatment protocol. Meticulously designed training modules and training materials which includes training documents, animated PPT, short videos, bedside training handbook, evaluation, questionnaires, online support modules and other small details of patient care as a short-term fellowship is essential. Community health planning related exposure also should be part of the curriculum. A university recognised certification would well equip the care workers to serve at their respective LF care units. Centres for disease control and prevention, Atlanta(CDC) adopted a strategy of integrating the lymphedema management into the curriculum for medical staff to achieve a successful nationwide MMDP programme in Togo, Africa¹⁷. Quicker nationwide scale-up is achievable if integrative medicine fellowship certification is approved. A short course of fellowship and certification programme attached to training and re-orientation would motivate health care team and encourage sustainability of MMDP even after complete elimination of LF as a public health issue.

Experience of IAD and situational analysis done by CCRAS have shown that lymphedema with *Vata*, or *vatha Kaphadosha* dominant features, within 5 litres in limb volume, correlated to International Society of Lymphology (ISL) grade 2 late or grade 3 (stony hard limbs) but do not frequently suffer from complications or co-morbidities. Lymphedema with *Kapha pitta* or *kapha Vata* dominant features, between 5 to 12 litres in volume and usually ISL grade 3 without major complications like ulcer, eczema, no recent ADLA, and patients with co-morbidities like hypertension, varicose veins and venous incompetence, and osteoarthritis. While lymphedema with morbid *Kapha* dominant (huge limbs) or morbid *pitta* dominant (recent ADLA, discharge, bullae and ulcers) features and above 12 litres; ISL grade 3 lymphedema with complications as a non-healing ulcer, eczema that require specialised skincare associated with gait abnormalities. Patients presenting with ADLA and patients with severe osteoarthritis, renal, endocrinal, obesity, cardiac issues and some venous insufficiency would require referral. Non-filarial lymphedemas are of different types and often require allopathic interventions to diagnose and manage

their long-term co-morbidities. Health care team managing LF as a public health programme requires orientation training to recognise all issues related to lymphedema.

Synthesis of outcomes of the AYUSH based NHP should be part of the training, monitoring and evaluation process. It will require frequent visits to the LF care units and evaluate the program such as treatment procedure, patient's reaction, additional infrastructure facility, and data management. Health care seeking behaviour of LF patients could be part of the study. Regular feedback and updates can upgrade the skills of the treatment team. Customised open medical records system (www.bahmni.org) with central data management and the analytic system would allow for tweaking the strategies and methods if required.

Demonstration Centre for lymphedema management:

Although IM protocol for LF is the current best standard of care and culturally suitable for endemic Indian villages, there are further research opportunities on MMDP. It was discussed in a priority setting partnership on future research in lymphoedema supported by the Department of Health Research, Government of India¹⁸. International experts visiting the IAD have observed that in several respects the programme is more successful than they have experienced in their departments¹⁹. It is important to try and explain why this is so. It is likely to be explained by the contribution of Indian systems of medicine, mainly the 'Ayurvedic Herbals' used for soaking the limbs or oils used for massage and possibly the frequency timing sensitivity and friendliness of counselling. More needs know about antibacterial and anti-inflammatory effects. So far, the IAD has measurements of disease status but only limited research into the mechanisms underlying such success. In Oxford the Department of Experimental Psychology explained how the brain be trained to be anti-inflammatory by the messages it sends to the Limbic system²⁰, sharing some of the features of both the ayurvedic and homeopathic questioning of the patient, yoga's mindfulness and control of the autonomic nervous system and the release of endorphins may also be a feature of a careful and friendly interview.

As the part of NHP lymphedema care and research

demonstration centre required to increase access to IM speciality treatment in underserved areas by providing front-line health care workers with the knowledge and support to manage lymphedema. It would enable doctors to provide best-practice care to underserved people all over India and developing nations. Demonstration unit should set the standard of care and serve to tweak the programme for regional healthcare in India by fully integrating into the public health system and willing private care facilities. A certification programme supported by a university as a fellowship leading to 'clinical lymphologist' and 'lymphedema therapist' would attract young professionals and sustain the programme in the long term. The training could be six months open course. It should comprise of theory and bedside training in the demonstration centre, postings in nodal centres, field training in the peripheral LF care units, community management modules, and research experience. Online training to fortify the re-orientation should be part of the fellowship programme. The programme must be rich in scientific updates enriching 'Care technology'²¹ (integrative medicine: biomedicine and ayurveda) but also teach how such technology must be rich in 'Care attitude'²¹ (of holistic ayurveda and yoga) in order to achieve maximum benefit.

Conclusion

Currently, 40% of the world's LF burden is in India. AYUSH based IM treatment is lymphedema self-care, locally available, low-cost and culturally acceptable. It does not require expensive high technology tools. Any complications associated lymphedema are rarely fatal *if recognised early*. Dramatic outcomes showed in the clinic, and community-based studies (Figure) are indicators for the sure success of AYUSH mainstreaming for one major disease burden of India. The decreasing popularity of AYSUH system²² for want of demonstrable, quick, outcomes comparable to biomedicine will get a significant boost due to the successful LF-MMDP pan-India implementation of IM protocol.

Indian innovation of IM, albeit received thrift funding²³ achieved paradigm shift of the treatment of Filariasis toward the Innovative Care for Chronic Conditions (ICCC)

Result after Integrative Treatment



Baseline:18-09-2019

Discharge:09-10-2019

of the WHO²⁴. It is now helping thousands of patients to step out of the neglect. Ayurveda is local, frugal and individual patient-centred²⁵. The public health programme to be effective in developing countries to treat the large disease burden of Lymphatic Filariasis should establish LF care units alongside end points such as the AYUSH Health and Wellness Centres targeted under Ayushman Bharat scheme in India. IM protocol for LF is the best available current tool that meets all these requirements and easy to implement for operational reasons and is ready for adoption for nationwide implementation.

Acknowledgements

We are grateful to honourable Minister of Health and Family Welfare, Government of India for appreciating integrative medicine protocol for LF and tweeting picture officially on the 30th October 2019

<https://twitter.com/drrharshvardhan/status/1189479869094100993?s=08> and <https://youtu.be/aYHeWP0ILk> as accessed on the 26th March 2020

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Source of Support : None
Conflict of Interest : Nil