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A Comparative Clinical trial on trophic ulcers of Leprosy: Ayurvedic management was promising!

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Abstract

Introduction: *Trophic ulcers in Leprosy patients is the major cause of disability. Ulcer Management by Modern Western Medicine has remained far from effective.*

Aim: *To examine the effect of Ayurvedic treatment on healing of trophic ulcers vis a vis conventional treatment.*

Methodology: *A non randomized comparative clinical trial on trophic ulcers in leprosy was undertaken. There were 31 study subjects selected from Dr. Bandorawalla Leprosy Hospital, Kondhwa and there were 31 subjects from two leprosy homes as control group. Criteria of selection of the patient was the age of planter ulcer was > 1 year. The study subjects were given Ayurvedic treatment and the control subjects were treated by conventional line of treatment. The area of ulcer of study group was 5.5 times more than the size of control group subjects.*

Results: *There was 76.84% improvement was noted in study group while in control group there was 43.24% improvement noted and further the average size of ulcer increased by 1.52%. In study group 89.47% ulcers showed more than 50% improvement as 34/38 ulcer showed the improvement,* $\chi^2 = 16.00, p<0.001$ *Statistically Highly significant.*

Conclusion: *The study proved that the Ayurvedic treatment may be a better alternative for treating trophic ulcers in Leprosy.*

Keywords: *Trophic ulcers in Leprosy, Ulcer management in Leprosy, Mahakushta, Ayurvedic management of Dushtavrana.*

Introduction

The present scenario of Leprosy is far from satisfaction. There were 127558 new leprosy cases detected worldwide in 2020, according to official figures received from 139 countries from the 6 WHO Regions. This includes 8629 children below 15 years. The new case detection rate among child population was recorded at 4.4 per million child population. Among the new cases 7198 new cases were detected with grade-2 disabilities (G2D) and the new G2D rate was recorded at 0.9 per million population[1].

Leprosy may not be a public health problem in government point of view but the sufferings of leprosy patients persist to a great extent leading to disability. Santoshdev P. Rathod et al observed that new deformities continue to develop in certain forms of leprosy even after release from treatment. Long-term & regular follow up of patients who have been released from treatment is really required[2].

Wrist drop, foot drop, trophic planter ulcers, nasal and eye deformities are commonly encountered. Nayak et al reported that trophic ulcers was the commonest deformity (21.73%), followed by claw hand, foot drop, madarosis, claw toes, lagophthalmos, ear lobe deformity, facial palsy, and finally nose deformity[3].

Chronic ulcers are commonly encountered in Leprosy patients and is a major cause of disability. Chronic ulcers in the sole of foot are Trophic in nature and the basic factor in their production is the involvement of Posterior Tibial Nerve, the affection of this nerve producing loss of sensation on the sole of foot[4]. Repeated injury & pressure of body weight acting on the denervated insensitive sole produce ulcers which are known as trophic ulcers. The ulcers get secondarily infected & may result in destruction of underlying bones & degeneration of joints. The management of patients with trophic ulcers and their consequences is difficult not only because it is a recurrent and recalcitrant problem but also because the pathogenesis of the ulcer maybe different in each case[5].

Aim of the Study

The present clinical trial was undertaken to find the effect of Ayurvedic treatment on Trophic Ulcers of Leprosy and to compare efficacy of treatment with current line of conventional treatment.

Material & Methods

This study is comparative non randomized clinical trial undertaken in Dr. Bandorawalla Leprosy Hospital, a 350 Bedded Govt Leprosy Hospital, 15 kms away from Pune. The Control group was from Leprosy Home at Dudulgaon, near Alandi - 22 kms from Pune and from Leprosy Home at Nerali, 5 kms away from Nanded (Maharashtra).

Criteria for selection of patients

1. The age of the ulcer was to be 1 year or more.
2. The ulcers were not to be very deep, affecting bones.
3. Willingness to undergo the trial with readiness to follow the guidelines.

31 Patients from study group & 40 patients from the 2 Leprosy Homes were selected. 9 patients from their Leprosy Homes left home before completing the study period. Thus the number of subjects in study group and control group remained equal i.e. 31patients.

Study period - March to June 2004

The study subjects were physically examined & their ulcerative wounds were noted in terms of site, size, shape, discharge, floor, walls etc. Their random Blood sugar was carried out routine Haemogram, Urine examinations were carried out. Similarly the control group subjects were physically examined and ulcers were noted as done for the study group subjects.

Table No.1 Comparison of study subjects and control group subjects before trial

Particulars	Study Group			Control Group		
	Male	Female	Total	Male	Female	Total
	21	10	31	22	9	31
No. of Ulcers	28	10	38	26	11	37
Infected Ulcer	4	1	5	4	1	5
Diabetes	3	0	3	1	0	1
Type of Leprosy- Pauci Bacillary (P.B)	13	7	20	8	4	12
Type of Leprosy- Multi Bacillary (M.B.)	8	3	11	14	5	19
Average age - 58.19 yrs				**Average age - 54.00yrs**		
Median age of ulcer - 20 months				**Median age of ulcer - 24 months**		
Average area of Ulcer - 13ccm				**Average area of Ulcer - 2.36ccm**		

Type of Ulcers (Study Group):
Occurrent - 3
Recurrent - 32
Non healing - 3

Type of Ulcers (Control Group):
Occurrent - 5
Recurrent - 30
Non healing - 2

Local treatment - Study Group

The ulcers of study group subjects were washed by the co-patients under supervision of Anjan Dey-a physiotherapist, with decoction of skin of Banyan tree, (Ficus bengalensis) Udumber (Ficus glomerata) & Pipal tree (Ficus religiosa). The skin of these plants contain anti inflammatory, antibacterial & healing facilitator properties (Ref Bhav Prakash) due to presence of Tannin, Silica, and Phosphoric Acid. Every alternate day the infected ulcers were washed by cow's urine that has antibacterial properties.

The ulcers were dressed with *Vran shodhan* oil which contained Haridra (*Curcuma longa*), Manjista (*Rubia cordifolia*), Nimba (*Azadirachta indica*), Madhuyashti (*Glycyrrhiza glabra*, Darvi (*Berberis aristata*), Trivarta (*Merremia turpethum)*, seed of Tila (*Sesamum orientale*) & Saindhav (*Rock salt*). All of these *dravyas* have antibacterial, antileprotic, antislough properties and the oil itself produce the facilitating effect to healing.

On appearance of granulation tissue, the ulcers were dressed with *Vranropak oil* that contain extract from Vat (*Ficus Bengalensis*), Kadamb (*Nauclea paryiflora*),Udumbar (*Ficus glomerata*), Kanher (*Merium olender*), Ashwattha (*Ficus religiosa*), Ark (*Calstropis procera*), Vetra (*Calamus Rotang/Casmus rascila*), Kutaj (*Holarrhena Antidsenterica*), Plaksha (*Ficus viranus*).

In the final stage of healing the ulcerated wounds were dressed by dry Triphala powder which helped in healing of the ulcers at faster rate.

Systemic treatment - study group

The study subjects were given Musta & Triphala 5 gm each twice daily. Triphala is a mixture of *Emblica officinalis, Terminalia belerica, Terminalia chibula*.

There were 3 diabetics in the study subjects. They were given *Mandur-bhasma/Ash, shilajeet and Trifala* in 1: 4 : 24 proportion; dissolved in decoction of Manjista (*Carthamus tinncorius*) The resultant solidified mixture is given in the form of 1 gm tablets given twice daily.

Five study subjects with infected ulcers were given turmeric (Curcuma Longa) 2 gm twice daily, as turmeric has antibacterial, antioxidant properties accepted by modern science too.

They were given Sukshma Triphala, in which the properties of Triphala are enhanced to number of times & acts as an antibiotic. This treatment with Sukshma Triphala was stopped when the infection was controlled & the patients were continued with Musta & Triphala.

Local Treatment (Control group)

The ulcerative wounds were washed by by the co-patients by savlon/ dettol, cleaned & dried & applied Soframycin ointment locally and dressed by sterile gauze and bandage.

The infected wounds were washed daily by the co-patients with Eusol, dried & dressed with Magsulph - glycerin combination.

Systemic Treatment (Control group)

Control group subjects with infected ulcers were given antibiotics, anti-inflammatory drugs like Aspirin, Ibuprofen, Voveran (Dichlofenac) with Vit- C, which helps in faster healing.

The patients under anti diabetic treatment were continued with the same anti-diabetic treatment. The patients were asked to take bed rest & not to do physical exertion.

The study subjects were examined by the researcher once in a week. The control group patients were continued to be seen once in a week by their doctor. The Control group subjects were evaluated by researcher at the end of study period.

Observations and Results

Table No.2: Comparison of study subjects and control group subjects after trial

Particulars	Study Group			Control Group			
	100%	>50%**	30-49%	100%	>50%	30 to 49%	No improvement
Improvement	8/38	34/38	4/38	3/37	16/37	1/37	20/37
%	21.05%	89.47*%	10.52%	8.10%	43.24%	2.7%	54.05%

*** χ^2= 16.00, p<0.001 Statistically highly significant. **Inclusive of 100% improvement.**

Table No.3: Comparison of improvement in size in study group and control group

Study Group		Control Group	
Before trial	**After trial**	**Before trial**	**After trial**
13 ccm	3.01ccm	2.36ccm	2.40ccm
76.84% improvement		-1.52% improvement (deterioration)	

Important Observations

1. The ulcer of study group was 5.5 times bigger in size (i.e. the ulcer area of study group was 13 ccm while the ulcer size of control group subject was 2.36 ccm). The size of ulcer of study group reduced from 13 ccm to 3.01 ccm while the size of ulcer of control group subjects was 2.36 ccm, which in fact increased to 2.40 ccm.
2. 89.47% ulcers showed more than 50% improvement in the ulcer of study subjects as 34/38 ulcers showed the improvement**, χ^2= 16.00, p<0.001 Statistically highly significant,** 8/38 ulcers are completely healed. The control group showed 43.24% improvement as 16/37 ulcers showed improvement & only 3/37 ulcers were completely healed.
3. There were 3 diabetics in study group who showed 96.19%, 95% & 38.46% improvement in their ulcers. The control group had one diabetic who did not show any improvement.
4. In the study group there were 5 infected ulcers out of which 2 showed complete (100%) healing and the rest 3 showed more than 70% improvement. In the Control group out of 5 infected ulcers, only one showed more than 50% improvement & there was no improvement in other 4 infected ulcers.
5. The study subjects showed marked improvement in their other ailments like hyper acidity, chronic rhinitis, chronic constipation & their overall health improved.

Discussion

This is probably the first study to compare the effect of Ayurvedic treatment with current Conventional line of treatment on trophic ulcers of Leprosy. Part of the findings of the study was published in Aryavaidyan in the year 2010[6]. The management of trophic ulcers in conventional medicine is far from satisfactory. Combination of Injection and Topical Platelet Rich Plasma was tried in isolated cases[7]. But we cannot label any gold standard treatment for treating trophic ulcers in leprosy in the conventional Medicine.

Sushrutacharya mentioned various types of Ulcers which are Kashtasadhya[8] i.e. difficult to heal in the following verse:

Kushtinam Vishjushtanam Shoshinam Madhumehinam I

Vranah Kruchhren Sidhyanti Yesham Chaapi Vrane Vranah II Su.Sutrasthan 23/7

Kustha (ulcers in Leprosy)., *Dushivishaj vran* (Poisonous/Chemical ulcers) *Prameha* (Diabetic ulcers), *Shoshi* (Ulcers in Mauns-Kshay as seen in Sarcopenia) and *Vrane-vranah* (recurrent ulcers) are *Kashta sadhya* (difficult to heal).

In the classical texts there has been mention of use of bark of Panchvalkala namely Vata (*Ficus bengalensis*), Udumbar (*Ficus glomerata*), Ashwattha (*Ficus religiosa*), Pluksh (*Ficus virance*), Pippalbhed /Hibinuxvs (*Thepasia populnea*). These trees are *Kshiri vriksha*, have d*eerghjeevi* (long life). Their properties are *Grahi, Sheetal, Vran, Shoth, Visarp nashak*.(Bhavprakash Nighantu) Out of these Panchvalkal, first 3 were easily available in the vast campus of study site and therefore they were used free of cost.

Vata (*Ficus bengalensis*) : Its properties are mentioned in Rajnighantu as follows[9]:

Jwardah-Trusha-Prameha Vran Shof Apaharak.....II

Uses of Udumbar (*Ficus glomerata*) have been mentioned as Vrana nashini (Curing ulcers) in Rajnighantu as follows[10]:

Udumbar Twacha Sheeta Kashaya Vran-nashini....II

Similarly use of Ashwattha (Ficus religiosa) in wound management has been mentioned as follows[11]:

Vrane Ashwattha twak-kakumoudumbara Ashwattha....I

In the systemic treatment of the study subjects we used Mustak/ Musta (Cyperus rotundus). Musta (Cyprus rotundus) acts as appetizer & removes the excessive secretions *(Kleda)* from the body.Classical texts have mentioned Musta having Deepaneeya and Pachaneeya effect as follows [12]: **Mustam Katu Himam grahi Tiktam Deepan-Pachanam.....II Raj Vallabha**

Along with Musta we gave Triphala, which is a mixture of equal parts of Emblica officinalis, Terminalia bellerica and Terminalia chibula. Triphala corrects vitiated Kapha and Pitta; is very effective in Diabetes (Prameha), Kushsta (Leprosy and other skin diseases), Eye diseases (Netravikaras) as mentioned in following verse:

Triphala Kapha-Pittaghno Meha Kushsta hara sara I[13]

Emblica officinalis contains Tannin, Calcium, Iron, carotene, thiamine which helped in healing the ulcers. Ayurved mentioned that it contains all the Rasa (secretions) except salty one. It has effect on nerve conduction & facilitates memory & intelligence.

Terminalia bellerica acts by rapid healing of ulcers. It has anti-inflammatory & astringent properties.

Terminalia Chibula removes the imbalance caused due to various factors & restores body to health. It has digestive, diuretic and astringent properties. It has special effect on Diabetes (Prameha), Leprosy (Kustharog), Ulcer, Swelling etc., as mentioned in Dhanvantariya Nighantu in the following verse:

Meha Kushsta Vran Chhardi Shop VatastraKrichhajeet I[14]

We have given Haridra (Curcuma longa) to 5 study subjects with infected ulcers. Raj Nighantu mentioned the medicinal properties including ulcer healing properties of Haridra/ Turmeric in the following verse:

Haridra Katu-tiktoshna Kaphavataastra Kushtanut I

Meha-Kandu-Vranan hanti Dehavarna Vidahini II Rajnighantu[15]

Limitations:-The study subjects were to be given special diet but due to unavoidable circumstances this was not possible or else the results could have been even better. The study subjects were told not to add extra salt in the diet & not to consume pickle.

The conditions at Dr. Bandorawalla Leprosy Hospital were not very different from these 2 sites of Control groups. The hospital was having

inadequate infrastructure one part time doctor & one Male Nurse only. The patients themselves carried out minor work like cleaning, sweeping, dressing etc. However study subjects were not given manual work and rest was given to them. The study subjects were unaware of the treatment given to control group subjects and vice versa.

Conclusion

1) The ulcer in study group receiving Ayurvedic treatment showed quicker and better healing than that of control group subjects receiving conventional treatment.
2) The area of ulcer of study group was 5.5 times more than that of the Control group subjects. Yet there was 76.84% improvement noted in them while in control group there was 43.24% improvement & the average size of ulcer increased by 1.52%

Recommendation

1) This therapy may be advocated for treatment of ulcers in Leprosy & may be communicated to all Leprosy patients & Institutions treating Leprosy patients.
2) The diabetic ulcers are neuropathic in nature. This therapy may be tried in such ulcers. A separate study may be undertaken to see the efficacy of the therapy in diabetic ulcers.
3) Director General of Health Services of Maharashtra has accepted the findings of the study vide his letter dated 15.4.2005 and the protocol was agreed to be circulated to all Civil Hospitals, Rural Hospitals , Leprosy Hospitals and Leprosy Homes.

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Conflict of interest: None

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