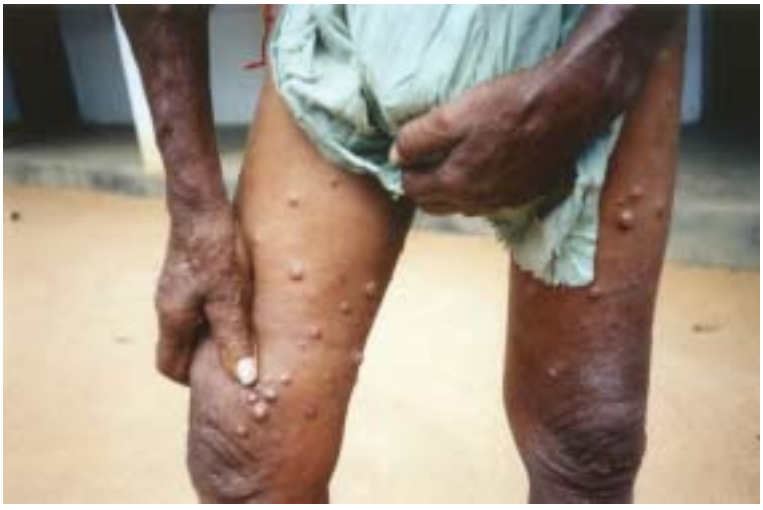
UPDATE
CONTINUING MEDICAL EDUCATION
Vol. 14 - No. 2 FOR PRIVATE CIRCULATION ONLY APRIL 2006

ARE WE MISSING RELAPSES IN LEPROSY?

Multi Drug Therapy (MDT) is believed to be one of the most robust regimens ever introduced for the treatment of any chronic infectious disease. It has proved to be highly efficacious with an impressive impact on the evolution of the disease in treated individuals and a remarkably low reported recurrence. It is paradoxical to assert but nevertheless true that the word relapse evokes a sense of satisfaction and concern in equal measures among passionate and dispassionate leprosy workers alike. A good majority of experts rest satisfied and is thankful that relapse in leprosy has a significantly low level of occurrence and still remains a manageable consequence. On the other hand, there is a sizeable section of alarmists who do not hesitate to caution us against complacency and challenge the contention that relapse is not a serious problem because of the simple reason that programmes do not look for it and therefore do not report it. Relapse, therefore, remains a point at issue in leprosy.



When one uses clinical criteria alone for diagnosis and classification and duration of treatment for fixing the end point of treatment it becomes rather difficult to arrive at a consensus definition of relapse. Is there an entity called PB relapse (initially PB case relapsing as 'PB')? If so, can it be differentiated from another relatively common post-RFT event, reversal reaction? What is MB relapse in the absence of bacteriological status? While scientific puritans allege that many scientific elements have been sacrificed on the altar of leprosy control and the present practices are not evidence-based, field protagonists underscore the imperativeness of simplification of procedures and are convinced that the changes are nothing to whine about. But what is of concern to all is the response from the programme. Nothing is done because one believes that nothing should be or can be done!

Even though consensus definition of relapse has eluded right from the beginning of the programme, some attempts were made to collect data on relapse from the routine programme as well as from research projects. Wide range of relapse rates (2.8% to 14.3%) was reported after Dapsone Monotherapy. WHO collected data from selected centers on relapses after MDT. This was, however, a heterogeneous group that included cases which were treated till smear negativity and also those who were given 6 months or 24 months fixed duration treatment. The relapse rate among PB was 0.9% and among MB it was 0.6%. Other reports published subsequently indicated occurrence of majority of relapses often more than 5 years after RFT. The magnitude of relapses after 12 months MDT is not known.

The national programme has reported few relapses in the last two decades. Is the incidence of relapse really low? Several changes introduced in the programme especially in the last decade render collection of valid data on relapse difficult. Cases after release from treatment used to be kept

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Update is published quarterly in the months of January, April, July and October by DFIT as part of its CME Programme to keep the field staff abreast of the development in the field of leprosy & TB.

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under active clinical and bacteriological surveillance for 2 to 5 years depending on whether they were PB or MB. But a careful study of the records from a few NGO projects indicates that a majority of proven cases of relapse/ reaction were detected through self-reporting: very few cases were detected through active survey. The number of relapses so detected were so few that it was felt that the whole exercise of active surveillance was not fruitful. Post RFT surveillance was, therefore, given up. With classification based on simple number of skin lesions smear examination was considered to be redundant and therefore it was also given the go by. Leprosy control programme that started as a vertical programme became integrated into general health. All the procedures were simplified to facilitate easy implementation by the general health staff. The programme stopped collecting information on relapse. It was removed from the patient card. The programme introduced validation of new cases as a means of improving diagnostic efficiency and of reducing leprosy burden. Patients who had had treatment before and presented with signs and symptoms of leprosy were, more often than not, either not treated or if treated were removed from the register as reregistered cases. All these changes mean that one is forced to wonder whether incidence of relapse is really low or one is missing relapses. There is an increasing number of reports from the field indicating the hastiness of staff in removing cases presenting with signs and symptoms of leprosy and had reportedly taken treatment before but who were on later examination by experts found to be smear positive relapses. The number of such cases may be low but one should not miss them because it gives us an opportunity to study them and prepare us for any eventual possible resurgence. Fortunately, all the cases that have reported with recurrence have responded extremely well with conventional treatment with MDT. It means resistance to Rifampicin is infinitesimal. "Is it or will it remain so", ask the alarmists. They point out that with self administered intake of dapsone and clofazimine (the drugs which can take care of Rifampicin resistant mutants) where regularity cannot be guaranteed, one cannot rule out the possibility of emergence of Rifampicin resistance. Moreover, there are very few centers in the world which are looking for Rifampicin resistance.

Observers point out that non-reporting of relapse does not mean nonoccurrence. If you don't look for it you don't find it. Let us start looking for it. The programme needs to identify referral units where smear examination can be performed and a definitive diagnosis of relapse can be made, build the competence of the staff at these centers through appropriate training with adequate follow-up support and introduce 'relapse' in the information system so that data on the important but hitherto overlooked event is captured and reported. In addition to introducing measures to look at relapses in the routine programme it is also important to undertake special efforts. Prospective study of relapses is difficult to carry out and is not practical. Instead, attempt can be made to collect data through retrospective study in which a sample of patients with leprosy treated about 5 years back from selected districts are followed through clinical and bacteriological examination. It is also important to identify a few well-established laboratory centers which can study Rifampicin resistance. Information collected through these efforts will be useful in getting an insight into the problem and enable us to prepare ourselves better for any eventuality.

Relapse is a distressing and desolating event. It is the responsibility of the programme to deal with it in the best possible way. To ignore it citing the rarity of its occurrence is certainly unethical.

DAMIEN PERSPECTIVES

(Translation of an article from "Damien Perspectives" Compaque 2006)

Dr. Claire Vellut

In January 1953, a violent storm damaged the Belgian seacoast. The country made an appeal for International help. Jute bags were needed. India responded by sending lots of them.

Some well – meaning people got together and decided to thank India for the timely help. Thus was created "Belgian Foundation for Leprosy". The plan and policy was to initiate a leprosy control centre, equip it, maintain it, and train the staff and hand it over to the Indian Government after 5 years.

Franse Hemerijckx, a leprologist from the Belgian Congo was approached for the project. He accepted with enthusiasm. He met 3 Belgian ladies (2 nurses and 1 doctor) at New Delhi. They decided to work as a team. Dr. F. Hemerijckx selected the place: Polambakkam, a village in an endemic district of Tamil Nadu, at a place where Dr.R.G.Cochrane had established a Leprosy Epidemiological centre cum night segregation centre in 1937. He decided to follow the National Leprosy Control Programme (NLCP) based on the 3 principles – survey, education, treatment. He gave it a very large extension (810 villages). The paramedical workers, boys and girls from nearly villages, were the pivots of the programme.

The Paramedical Workers lived in the villages for which they were responsible. The medical team visited the treatment points (clinics under the trees) every month. The management was very good. Within one year, 12000 patients were detected and treated. By 1970, more than 45,000 had benefited from the centre.

At Polambakkam itself, the establishment included a hospitalization ward (50 beds) with reconstructive surgery and physiotherapy facilities, a well-equipped laboratory and a training centre for paramedical workers. Later on, Anandapuram, a home for homeless, severely mutilated patients was established.

Government and NGO:

In July 1960, the centre was handed over "lock stock & barrel" to the then Madras State. The staff was integrated in Govt. Service. I was asked to be in charge of the Centre. I held that post till July 1980.
In 1964, the Damien Foundation was registered in Belgium (DFB) and in 1992 it was registered in India as "Damien Foundation India Trust (DFIT).

In 1978, the Damien Foundation was the first ILEP member to sign a memorandum of understanding with the Govt. of India. It included, logistic support (drugs, microscopes and vehicles), training of personnel, establishment of leprosy control centres in 7 States. These centers were handed over to the respective state government after 5 years.

Along with the cooperation with government, the Foundation sponsored several NGOs to start or to continue programmes of leprosy control giving them financial support and technical expertise on the condition that these NGOs, would follow the general policy of NLCP / NLEP.

Towards North:

In 1979, while on a WHO Consultancy, I was shocked by the number of leprosy cases in Bihar. I found myself in the same situation as in Tamil Nadu in the fifties. The Bihar Government was not involved, some local NGOs of Gandhian inspiration who were doing leprosy work, were overburdened. DF Opened a centre at Dehri-on-sone. It attracted a large number of patients and received a solid local cooperation. The state authorities became aware of the seriousness of the problem. It initiated a training centre for medical officers at Dehi-on-sone.

The Leprosy situation in South India was stable and good information system made the public aware of signs of the disease and its treatment. There was voluntary registration of cases and the multi drug therapy was followed. Many medical officers and NMS, who were either free or had retired, accepted the challenge to work in Bihar. Bihar was a difficult state with 10 crores of inhabitants and the administrative structures were weak. 25% of the estimated number of leprosy patients of India lived in that state.

The public and the health services were ready to collaborate. DFIT posted one medical officer, one NMS, one local driver

and one vehicle in each of the districts allotted to them. The district technical support teams (DTST) were formed. Their priority was the training of the general health staff to detect and treat leprosy. They were helped by the staff of NLEP which have always been inadequate in number. Seminars and workshops were organized for health services from the district chief medical officers to the village health workers. Special attention was given to the training of the laboratory technicians to ensure reliable bacteriological examination. Later on prevention of deformities (POD) training was given to all. Recently the surgeons of Patna and Dharbanga medical colleges started doing reconstructive surgery under the guidance of Dr.Jacob Mathew of DFIT.

Also Tuberculosis:

In 1996, first some NGOs, then some state governments wished to link Tuberculosis Control with Leprosy control. DFIT initiated training of its officers and staff to a systematic approach to Tuberculosis Control.

Andhra Pradesh, Karnataka and Bihar requested DFIT involvement in the programme. The DTST along with the PHC staff planned and monitored the DOTs programme in the districts allotted to DFIT.

Priority is given to training of the field staff and monitoring the quality of sputum microscopy.

In Tamil Nadu, leprosy programme was integrated in general Health Services in 1997, Tuberculosis programme remained as usual at PHC level. The DFIT sponsored NGOs became referral centres for leprosy and tuberculosis. Their staff worked with the PHC workers for detection and treatment, including prevention and care of deformities.

Retrospective:

When we review these 50 years of Belgian cooperation with India, we feel satisfied with the work done. Of course some unavoidable mistakes have been made but I would like to concentrate on the positive aspects and to mention 3 factors which in my opinion have characterized our action in India.

1. Damien Foundation's attitude towards the Government (Central Govt. as well as State Govt.) allowed us to have continuous and fruitful dialogue with them on the priority and allowed us to be flexible in our action. Today Dr.P.Krishnamurthy, DFIT Secretary and his colleagues are important members of Leprosy and Tuberculosis Commissions at the national level.

2. Good understanding between DFB & DFIT has been the strength of our association. Attentive listening, fairness and transparency have permitted rapid and efficacious answers to needs.

3. The faithful support of the Belgian people has been essential for DFIT's growth. This support was not only at the financial level but has been a common endeavour between two countries that love and respect each other. The services have always been personalized from the beginning when Belgian volunteers had worked at Polambakkam till recently when "Chantiers Damien" became involved in India.

For the future, we hope that in the same spirit, with the same commitment, we can march forward, keeping in view the needs that arise in the priority zones of Damien Foundation.

HAPPENINGS

Project visit by Mr.Luc Comhaire and Dr.Tine Demeuleanaere :

Mr.Luc Comhaire, the Project Manager and Dr.Tine Demeuleanaere, Medical Advisor from Damien Foundation, Belgium visited several projects supported by DFIT in India. They gave valuable suggestions and appreciated the efforts of DFIT.

Mr.Luc Comhaire and Secretary visited Nellore on 03rd and 4th March 2006

Dr.Tine and Dr.P.Vijayakumaran, CMA(S) visited Arisipalayam on 3rd and 4th March 2006

Mr.Luc Comhaire and Secretary visited Dharbanga and Madhubani districts.

Dr.Tine and Dr.Biswanath Prasad, CMA(N) visited Gaya and Nalanda districts.

Re-registration or Relapse ?

With emphasis on correctness of diagnosis and registration of persons suspected with leprosy, some times there is a chance that a person presenting with relapse is not treated. Here is an example,

A male patient by name Sadan Manjhi, aged 51 years in Wazirganj, Gaya, in Bihar, reported to PHC with infiltration and flat skin lesions all over the body on 26th August 2005. He had been treated with PB MDT for six months (for less than 5 skin lesions, no nerve involvement) in 1988 and had been released from surveillance on 19th August 2005. Earlier (seven years before) he had been treated with Dapsone monotherapy for two years from 1981 for multiple skin lesions. The staff at PHC insisted that since he had already taken treatment there was no need to restart MDT; it was definitely old case. They did not observe the skin lesions. Dr. Vijayakumaran, Chief Medical Advisor for DFIT, who was at the PHC at that time, examined the patient and suspected relapse. A skin smear was suggested. Smear examination revealed BI of 3.3 +. A diagnosis of relapse was made and MDT (MB) was started.

TB CONTROL PROGRAMME

Why do some TB patients default on treatment?

Default : A TB patient on DOTS continuously absent for 2 months or more

	Reasons	Actions required
1	Side effects of drugs	• Training to health workers on counselling • Proper counselling of TB patients prior to starting treatment
2	Feeling well after IP	• Proper counselling of TB patients prior to starting treatment
3	Long distance to MC / patient did not undergo follow up sputum examination	• Alternate arrangement to transport sputum specimen – by relatives or health workers
4	Long distance to DOT centre	• Arrange DOT provider convenient to patient
5	DOT provider is not convenient	• Arrange a suitable DOT provider in consultation with patient
6	No absentee contact	• DOT providers are to be instructed not to allow absenteeism. Inform STS / MPHS for immediate absentee contact action
7	Delay in starting treatment	• Treatment should be started with in 7-10 days after detection. • Hasten the process of address verification and identification of DOT provider.
8	Lack of supervision	• Supervision of health workers and patients by STS, MO-PHC, MO-TU • Supervision of MO-TU and STS by DTO
9	Irregular drug supply (IP & CP pouches)	• When a TB patient is started on DOTS whole treatment box should be supplied to the DOT provider.

Integration of POD service in Salem District : Success story

Mr. Appasamy, aged 63 lives with his wife Palaniammal aged 56, in a remote village Perieri in Talaivasal block, Salem. They were old patients of Hansen's disease with multiple skin patches but not properly diagnosed and treated. They took native drugs and approached a traditional village doctor. But the disease worsened: Mr. Appasamy developed ulcer in the foot and his wife developed reactions. Their two sons and daughter also developed skin patches. They approached a Public Health Centre in Talaivasal block and took Siddha medicine. Though Multi Drug Therapy was available in the same PHC, they were wrongly diagnosed and given Siddha medicine for three years. The social stigma due to the disease prevented them from getting their children married. The family was desperate as they tried and exhausted all treatments known to them and had given up.

During the year 2005, St Mary's Leprosy Centre, Arisipalayam, Salem implemented POD programme in Thalaivasal block PHCs. The Physiotherapist of the Project along with the Govt. PT trained the Village Health Nurse's of the block on POD activities. VHNs were asked to trace out cases with disabilities and update the existing patient list of the block. During this process, the VHN who went to Perieri village identified Mr. Appusamy and his family and screened them. All of them were diagnosed as cases of MB leprosy.

This matter was reported to the Medical Officer-PHC and Deputy Director Leprosy, Salem district. Then the team comprising of DDL, MO, Non Medical Supervisor, Health Inspector, PT and VHN visited this family and registered them under MDT and started the treatment. Mrs. Palaniamml was treated with steroids for her ENL Reaction; Mr. Appusamy was given training on Soaking, Scrapping, Oiling, and Dressing (SSOD). All the patients were closely followed up and in January 2006 the team evaluated them. There was tremendous improvement in the health of the family members, Mrs. Palaniamml's reaction subsided and Mr. Appusamy's ulcer had also healed completely. The whole family is very happy now.

The success of involving VHNs in Leprosy control activities proves that proper guidance and training to develop the skills of the staff will hasten the process of integration of Leprosy services including that of POD into General health service.

Self care for the feet: (ISSOD)

I : Inspect feet daily for signs of redness, injury. (Fig.1)
S : Soak the feet at least for half an hour in water. (To make the skin soft and supple) (Fig.2)
S : Scraping the hard skin (callous) using any rough stone.
(To remove hard skin and to even the edges of the wound) (Fig.3)
O : Apply oil (preferably Neem oil) while the skin is still moist. (To retain moisture on the skin) (Fig.4)
D : Dress with a clean, old cloth to cover open wounds. (To protect the wound from dirt) (Fig.5)
Use proper footwear **(MCR)** while walking. (Fig.6)

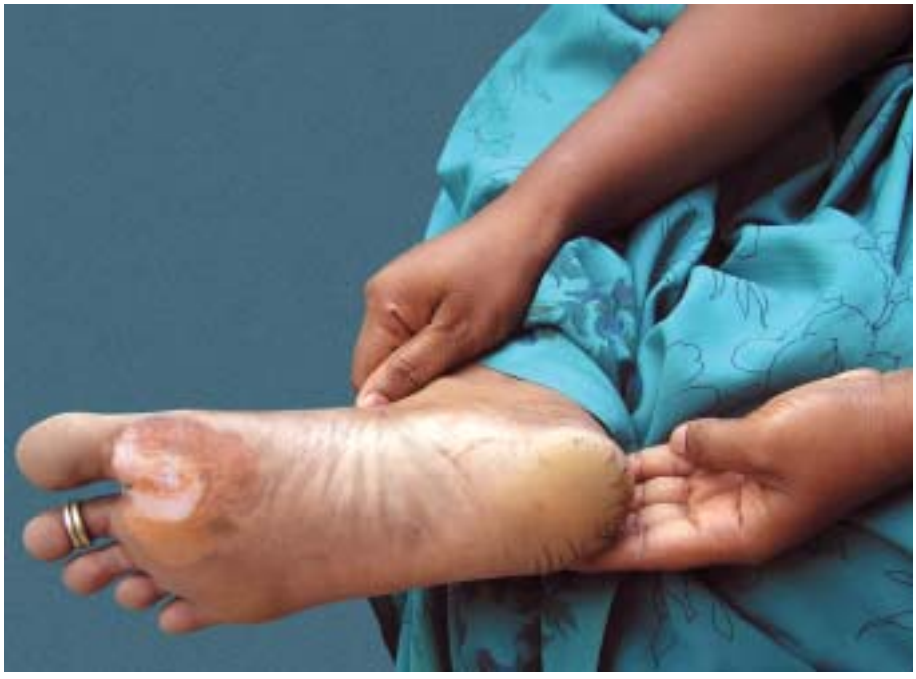

Fig.1. Inspect feet daily for signs of redness, injury.

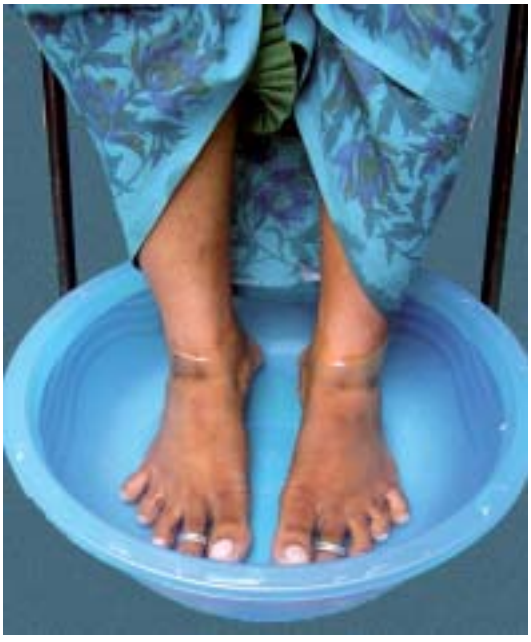

Fig.2. Soak the feet at least for half an hour in water. (To make the skin soft and supple)

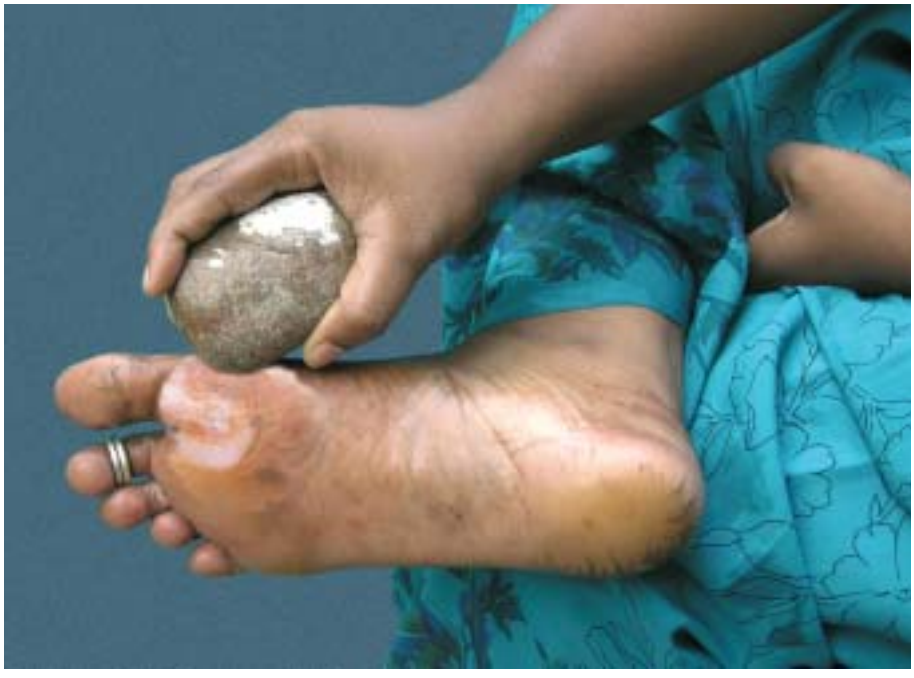

Fig.3. Scraping the hard skin (callous) using any rough stone. (To remove hard skin and to even the edges of the wound)

Self care for the feet: (ISSOD) - Contd. from page 7

Fig.4. Apply oil (preferably Neem oil) while the skin is still moist. (To retain moisture on the skin)

Fig.5. Dress with a clean, old cloth to cover open wounds. (To protect the wound from dirt)

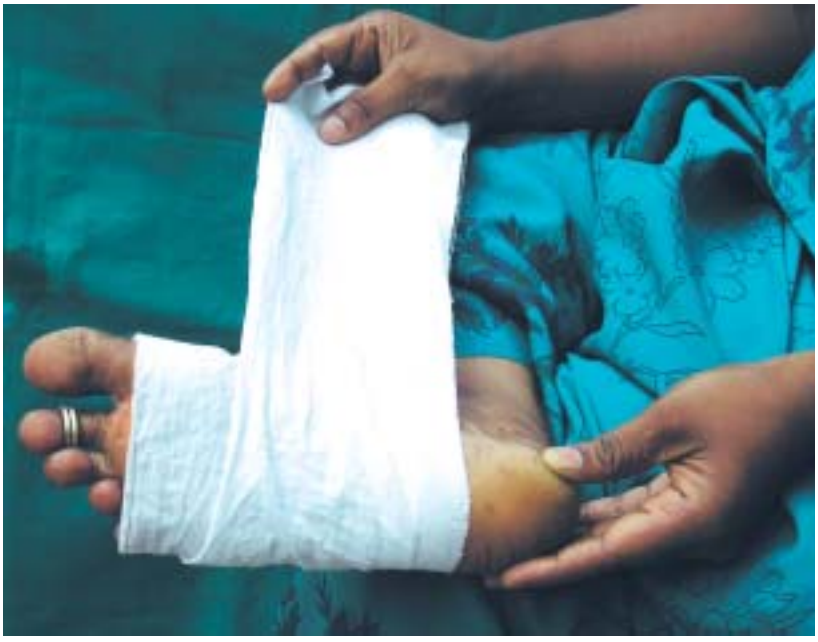

Fig.6. Use proper footwear (MCR) while walking.

Walk as little as possible, walk slowly and take frequent rests.
If ulcer is present, rest is essential.