

Delivery of MDT through blister calendar packs in leprosy eradication programmes— a multicentre field study (Phase I)

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Summary To overcome operational problems and improve patient compliance in leprosy programmes, DANIDA introduced blister calendar packs (BCP) to deliver MDT in four districts in India. A questionnaire study of 1470 patients from these districts showed that more than 90% accepted BCP and found them to be very convenient for domiciliary treatment. A similar study of 127 treatment providers indicated that delivery of MDT through BCP was found convenient to overcome logistic problems.

Introduction

One of the important factors for the success of the MDT programme is to obtain maximum compliance for pulse doses as well as for self-administered doses. Compliance is influenced by many factors. Of relevance here are a continuous and regular supply of all the three drugs and simple methods of preserving these drugs at the patients' houses without damage or loss. As the disease is still associated with social stigma, making drug delivery in a socially acceptable attractive form is an additional factor which influences patients' compliance. Other operational factors like easy storage, easy transportation without any loss or damage, easy accounting and preparation for clinics at control unit level could also affect the efficiency of the MDT programme in general.

To overcome operational problems in the field, delivery of antileprosy drugs through BCP similar to oral contraceptives was conceptualized as early as 1983.¹ Ciba-Geigy Basle (1986) designed and manufactured BCP following a WHO recommendation on MDT for multi- and paucibacillary forms of leprosy.²

DANIDA is assisting the National Leprosy Eradication Programme (NLEP) in India in four districts (Cuttack in Orissa, Salem in Tamil Nadu, Durg & Rajnandgaon in Madhya Pradesh). As an alternative strategy of drug delivery, it was decided to use BCP for an estimated 160,000 patients (MB 40,000 and PB 120,000) with the following objectives:

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Improved drug supply:

- Safe—no pilfering, no spoilage.
- Effective—right drug regimen is given.
- Efficient—easy drug delivery.

Improved patient compliance:

- Safe—self-protected, easy storage at patient’s house.
- Regular—self-monitoring possible.

Increased cost-effectiveness:

Pharmanova, Copenhagen designed and manufactured these packets for MB-adults (red colour), PB-adults (green colour) and PB-children 6–14 years (blue colour) suitable for the Indian MDT programme.³ As no published reports are yet available on evaluation of this alternative approach in improving operational efficiency of the programme, DANIDA decided to undertake a multicentre field study to find out: (a) feasibility of using BCP in the vertical leprosy programme; (b) influence of these packed drugs on patients and field staff; and (c) cost-effectiveness of using blister packs.

In this paper results of Phase I of the study are reported.

Material and methods

This multicentre study was designed in two phases:

Phase I. A structured questionnaire study was designed to obtain subjective impressions of patients and staff regarding the acceptance and use of BCP in a routine MDT programme.

Phase II. A study of patient compliance comparing patients receiving blister packs with patients in the same district receiving bulk drugs.

METHODOLOGY FOR PHASE I STUDY

- 1 Under NLEP-India, MDT is being delivered through a circuit plan (a circuit consists of 2 subcentres of 2 paramedical workers with approximately 40,000 population).⁴
- 2 Subcentres which had completed a minimum of 6 months’ treatment with BCP were selected randomly.
- 3 At the time of this study a total of 48,000 patients were given BCP in all the four districts. A total of 10,000 patients had completed 6 months of MDT in 105 subcentres. Out of these, 57 subcentres were selected randomly and 1470 (14%) adult patients were interviewed.
- 4 To overcome any bias, the interviews were conducted by volunteers not connected with the programme.
- 5 From the same subcentres 127 control unit staff were randomly selected for interview.

Table 1. Number of leprosy patients interviewed

No. of patients interviewed	Type		Sex	
	MB	PB	M	F
1470	615	855	947	523
%	42	58	64	36

Table 2. Impressions of patients on blister calendar packs (BCP)

Questions	No. of patients with positive answers	%
1 BCP are attractive	1433	97
2 Preservation and handling are easy	1449	99
3 Tablets could be taken out easily from BCP	1446	98
4 Drugs are not spoiled	1395	95
5 BCP helps patients to take drugs regularly	1357	92
6 Drugs are taken regularly	1362	93
7 Drugs are very effective	1351	92
8 Printed numbers on BCP are not understood	802	55
9 Instructions for preservation are not understood	996	68
10 Last tablet reminds the patient of clinic day	772	49

Table 3. Impressions of staff on blister calendar packs (BCP)

Questions	No. of staff with positive answers	%
1 BCP attractive	126	99
2 Easy to handle, transport and preserve	124	98
3 Attendance rate for pulse clinic increased	113	89
4 Regularity for self-administered doses increased	120	94
5 Tablet count shows correct self-administered dose	108	85
6 Clofazimine capsules stick inside the pack	74	58
7 Blister packs are not lost by the patients	109	86
8 BCP suits the circuit plan and pulse clinic	105	83
9 Drug accounting, dispensing and instructing patients easy with BCP	101	79
10 Time required for counting BCP for a clinic:		
(a) less than 1 hour	111	87
(b) 1-3 hours	16	13
11 Time required for counting and packing loose drugs for a clinic:		
(a) 3-5 hours	84	66
(b) more than 5 hours	43	34

Results and discussion

A total of 1470 were interviewed, 1213 (83%) had treatment for 6–12 months and 257 (17%) had more than 12 months treatment with blister calendar packs (Table 1).

1 These answers (Table 2) indicate that blister calendar packs were well accepted by the patients. They were attractive, could be preserved easily at home and drugs were not spoiled. Only 5% of patients reported that clofazimine capsules were sticking to the PVC and broke when removed.

2 More than 92% of the patients said that they were taking drugs regularly. More than 50% of the patients were not able to read the numbers and instructions written on the BCP. This indicates that there is further scope for improving the design of BCP. Perhaps their sequence could be given in pictorial form, i.e. showing arrow marks for directions, symbolic presentations for days, etc. Only 392 (27%) said that they could understand instructions written in English.

3 Of the patients 92% said that these drugs were very effective. This impression could be due to the attractive exterior of BCP.

The answers (Table 3) indicate that the staff of leprosy control units from all these four districts found that the BCP were attractive, easy to deliver and that less time was used in preparing for

clinics compared with using bulk drugs. This was based on their experience during the first 14 days of intensive therapy where all the drugs were delivered loose. The subjective impression of the staff on the increase in regularity is to be confirmed by an objective study which is in progress.

This preliminary study has shown that BCP were accepted both by the leprosy patients and the staff. The BCP design was suitable for the MDT programme and facilitated delivery of the right drugs by the colour of the packs. Drug accounting, storage and transportation was also found to be easier. These findings support our initial observations reported earlier.⁵

One reservation about the use of BCP on a mass scale would be the additional cost over bulk drugs. However, once economies of scale are achieved in the production of BCP, it is believed that the price differential will probably be no more than 15%.

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References

- ¹ Winsley BE, McDougall AC Browne KE. Chemotherapy of leprosy: 'bubble' or 'calendar' packs for administration of rifampicin, dapsone, clofazimine or prothionamide/ethionamide. *Int J Lepr*, 1983; **51**: 592-4.
- ² Ciba-Geigy. Bubble or calendar packs for multiple drug therapy in leprosy. *Lepr Rev*, 1986; **57**: 181-2.
- ³ Georgiev GD Kielstrup RW. Blister calendar packs for the implementation of multiple drug therapy in DANIDA Assisted Leprosy Control Projects in India. *Lepr Rev*, 1987; **58**: 249-55.
- ⁴ Government of India, Guidelines for Multidrug treatment in Endemic districts. Published by Leprosy Division, DGHS, New Delhi, 1986.
- ⁵ Revankar CR, Sorensen Birte H. Blister calendar packs for the treatment of patients in leprosy control programmes with multiple drug therapy. Letter to the Editor, *Lepr Rev*, 1988; **59**: 84.