

A RETROSPECTIVE STUDY OF "NON-COMPLIANT" PATIENTS IN CONTROLLED CLINICAL TRIALS OF -SHORT COURSE CHEMOTHERAPY

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Summary: In a total of 2,332 pulmonary tuberculosis patients admitted to 3 different short-course chemotherapy studies conducted during 1975-1985, there were 60 'non-compliant' patients who had received less than 75% of the prescribed treatment. A retrospective study was undertaken to find out the reasons for default in these patients since the Tuberculosis Research Centre has very stringent criteria of selection of patients for their studies, an adequate system of motivation of the patients and well organised infrastructure for retrieval of the defaulters.

Unwillingness for treatment was stated as the reason for default by 20 patients and adverse reactions to the drugs by 16 patients. Other major reasons given were pressure of work (14 patients), frequent outstation visits (13) and migration (12).

Introduction

The problem of drug default has been commonly observed whenever prolonged therapy has to be given. In tuberculosis, non-adherence to prescribed treatment could lead to treatment failure and development of drug resistance while the patient continues to transmit infection.

Treatment non-adherence poses many additional problems for the tuberculosis control programme such as, defaulter actions, retrieval efforts and change of chemotherapeutic schedules,

etc., which have an adverse economic impact due to increase in operational costs.

A retrospective analysis was undertaken of 60 'non-compliant' patients who had received short-course chemotherapy under 3 fully supervised, controlled clinical trials at the Centre during 1975-85¹⁻³ to find out the reasons for default in spite of the intensive defaulter retrieval procedures of the Centre following a very careful selection of co-operative patients and giving them intensive health education and motivation. Such efforts are not practical under programme conditions.

Material and Methods

At the Tuberculosis Research Centre, Madras, pulmonary tuberculosis patients who were permanent residents of Madras and were suitable for long-term follow-up and judged to be cooperative were accepted for treatment in the different controlled clinical trials. Suitability of the patients for inclusion in the trials was methodically assessed, initially by a medical officer, a social worker and a health visitor (HV) for 5-7 days. Initial home visits were made by a HV and a social worker to assess domiciliary stability, family set-up, socio-economic background including employment, income, details regarding previous treatment and patients' cooperation with regard to treatment, follow-up and home visits. Apart from these, the close relatives of the patients were also interviewed to ensure cooperation. For every patient started on treatment, a full list of addresses was obtained, namely (i) the patient's home address, (ii) the addresses of relatives and friends and details regarding how

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often he visited them, if employed, the place of work, (iii) if children were at school, their addresses and (iv) the address of his native place⁴.

The anti-tuberculosis chemotherapy in these trials consisted of fully supervised drug regimens containing Rifampicin for a period ranging from 2 to 6 months and the total duration of treatment ranged from 3 to 7 months. The due dates of drug administration were intimated to the patients in advances.

A patient is considered as "non-compliant" if he has received less than 75% of the prescribed chemotherapy during the scheduled treatment period.

A total of 60 (2.6%) non-compliant patients were identified as per the above criterion out of 2,332 patients admitted to 3 short course chemotherapy studies and efforts were made to elucidate the reasons for non-compliance from their case papers.

Various intensive defaulter retrieval procedures had been followed, namely repeated visits by health visitors/social workers/medical officers to the house/work spot/contact address of the patients and even outstation visits, if needed. If a patient failed to attend and if his or her house was found to be locked and the neighbours did not know where the patient (or the family) was, a systematic search was made with the help of various alternative addresses until the patient was traced.⁴

Periodic meetings had also been conducted among the clinic staff to discuss the non-compliance problems and suitable remedial measures had been taken.

Results

Pre-treatment characteristics

Of the 60 non-compliers, 54 (90%) were males, and 36 (60%) were in the age group of 25-44 years which is the most economically productive period of life. Twenty-eight (47%) patients had received treatment at the clinic of the Tuberculosis Research Centre while the

remaining 32 (53%) had treatment at our sub-centres located at different government hospitals in the city. The duration of stay in the city was more than 5 years for 53 (88%) patients, and 47 (78%) did not change their residence during the treatment period; 77% lived within 5 km of their treatment centre. Eighty two percent were married with families consisting of 5 or less members, 41 (68%) were daily wage earners, such as painters, construction workers etc., and 13 (22%) belonged to salaried class; 88% of these had monthly income of less than Rs. 300; 27 (46%) were used to taking liquor (14 occasionally and 13 frequently).

Pattern of default

The month of default and the rhythm of treatment are shown in Table 1. Thirty three (55%) patients held defaulted in the first month and another 21 (35%) in the second; thus, 90% of the default had occurred within the first two months. Of these 54 patients, 20 (37%) had defaulted on daily attendance, 17 (32%) on thrice weekly and 17 (32%) on twice weekly attendance. The remaining 6 patients had defaulted during the continuation phase; 5 on twice-weekly and 1 on once-weekly treatment. **Thus, it may be observed that there was no association between regularity and frequency of attendance.**

During home-visits, it was observed that 50 (53%) of the non-compliers were non-cooperative to the extent of hiding themselves or disappearing from the spot on seeing the Centre's vehicle in spite of motivation, repeated visits, a written compliance agreement (a health contract or "written commitment") and warnings given that they were not being regular in attendance and special efforts made for their retrieval including various monetary benefits such as reimbursement of travel expenses, compensation for loss of wages, diet and family assistance, ambulance and hospital admission provided for 36 (60%) of 60 defaulters.

Major reasons for default

The various reasons for default were obtained from the case records of the 60 non-compliant patients. Some of the patients had given more

Table 1. Drug collection pattern

Month of default	Daily	Frequency of drug collection			Total	
		Once Weekly	Twice Weekly	Thrice weekly	No.	%
1	13	0	9	11	33	55
2	7	0	8	6	21	35
3	0	1	4	0	5	8
4	0	0	1	0	1	2
Total default	20	1	22	17	60	100

than one reason for their repeated or continuous default (Table 2). Among these, 'unwillingness for treatment' marked first, and was given as the reason by 20 (33%) patients. 'Unwillingness for treatment' denotes their general disinterest or indifference and this might be due to their having to attend the clinic daily for the supervised chemotherapy. Adverse reactions to the drugs was given as reason by 16 (27%) patients. Other reasons were pressure of work by 14(23%) and frequent outstation trips by 13 (22%). Temporary absence of patients from the city was mostly because of business, family or social obligations such as vocational commitments, marriages, religious functions, death. etc., Twelve patients (20%) had migrated out of Madras. Alcoholism was found among 7 (12%). Lack of bus fare was given as the reason for default by 5, whereabouts were not known in 4 and fear of injections/blood

was the reason in 3 cases. Three patients took treatment elsewhere. Only 2 patients discontinued treatment because they felt well.

Discussion

'Unwillingness for treatment' (33%) was found among the more dissatisfied patients who did not want to adhere to the strict treatment schedule of the controlled clinical trial conditions. Generally, once the symptoms disappear, the standard of regularity also goes down considerably.

Next major reason given was adverse reactions to the drugs (27%). The patients in this group needed a change in treatment schedule in addition to reassurance and motivation by trained-health personnel. Next in order came pressure of work (23%) and frequent outstation trips (23%). Out of 60 non-compliers, 31 (65%) were daily wage earners, and 88% of the defaulters had very low monthly income of less than Rs. 300/. For them to spend a day in the clinic meant loss of wages. We could minimise the extent of their default by administering drugs either at home or at workspot or a more convenient place. For patients who leave home early for work and for those who are out of station often, 'health posts' to provide health care near their homes, at a time convenient to them, may be helpful.

Human nature being what it is, patients who take medicine regularly, voluntarily, without a break are not many⁵. The problem of non-compliance is bound to continue whatever action we might take. However, an understanding of the specific reasons can help to devise specific steps

Table 2. Major reasons given for non-compliance

Reason for non-compliance*	Patients	
	No.	%
Unwillingness for treatment	20	33
Adverse reactions	16	27
Pressure of work	14	23
Frequent outstation trips	13	22
Migration	12	20
Alcoholism	7	12
Lack of bus fare	5	8
Whereabouts not known	4	7
Fear of injections/blood tests	3	5
Taking treatment elsewhere	4	7
Felt well	2	3

* Multiple reasons were given

to reduce the problem, which cannot apparently be eliminated.

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