STATUS OF SMEAR POSITIVE PULMONARY TUBERCULOSIS PATIENTS AFTER CHEMOTHERAPY UNDER THE DISTRICT TUBERCULOSIS PROGRAMME*

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Summary : **In North Arcot district, where Short Course Chemotherapy (SCC) had been introduced in 1983, a cross sectional survey was carried out in respect of smear positive patients put on SCC or traditional regimens between April 1986 and March 1988. It was found that 19% of the treatment cards from the D.T.C. were in respect of duplicate registrations. The address given was inadequate in 13% of the cards. Only 69% of the smear positive patients had accepted short course chemotherapy and the rest were given traditional regimens. The cross sectional survey covered the period 6 to 36 months after the start of treatment. Overall mortality in patients with tuberculosis was 28% during 36 months. It was 3-5 times as high in those who had taken less than 50% of chemotherapy, irrespective of age. Thirty one percent of the patients were smear positive at the time of the home visit. However, among those who had taken 80% or more of chemotherapy, 20% on SCC and 26% placed on conventional treatment were sputum positive. Nonetheless, even among those who had taken less than 50% of chemotherapy about 58% were sputum negative.**

Introduction

Short Course Chemotherapy (SCC) regimens have been introduced in the National Tuberculosis Programme since 1983. The first district to benefit was North Arcot in Tamil Nadu. A fully intermittent twice weekly supervised regimen with Rifampicin 450 mg, INH 600 mg and Pyrazinamide 2 gms for the first two months followed by Rifampicin 450 mg and INH 600 mg for the next four months is in operation there. It was expected that introducing regimens of short duration will increase treatment compliance and, thus, contribute to improving the tuberculosis situation in the district.

The routine monthly returns from the district, however, have shown that the compliance to chemotherapy has only improved from about 25-30% with the traditional regimens to about 45% with the short course regimen. Besides, information on the bacteriological response to treatment or relapse among these patients is not available. Attempts at collecting the 'end of chemotherapy' and subsequent sputum specimens in these patients had been successful in only a small number of patients. Even this small success was not achieved in patients who got "lost" or those who did not complete chemotherapy. In order to evaluate the result of SCC under district programme conditions, it is essential to collect this information.

The study was undertaken to assess both the clinical and bacteriological status of patients u-ho were started on SCC or traditional anti-TB chemotherapy for smear positive pulmonary tuberculosis during a specified period (i.e. April 1986-March 1988) in the North Arcot district.

Objectives

1. To study the fate of smear positive patients started on anti-tuberculosis chemotherapy in a district.

2. To relate the fate to the amount of chemotherapy consumed, as well as to the status of case-holding i.e. those who discontinued treatment or got lost and those who remained under treatment till the end of treatment period

Methods

The study was a one point cross sectional

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survey and not a cohort analysis. Treatment cards of all the patients with smear positive tuberculosis, i.e. 'B' cases, were obtained from the District Tuberculosis Centre, Vellore. These cards were sorted Taluk-wise. The Peripheral Health Institutions in the district were then visited. The cards on hand were checked with those in the PHI records, and any omissions were added to our list.

Information regarding drug regimen, date of start of treatment, amount of drugs collected and place of residence was obtained from the collected treatment cards. The patients were then contacted in their homes and two specimens of sputum were collected (one spot specimen and one overnight specimen). At the time of the house visit, information on symptom status and subsequent chemotherapy, if any, was also collected. Sputum specimens were transported to the laboratory where they were examined for smear and culture for AFB. All positive cultures were tested for sensitivity to Streptomycin, INH and Rifampicin.

House visits were carried out between November 1988 and July 1989. Thus, the period after the start of treatment, when the patients were contacted in their homes ranged from 6 to 36 months.

Results

1. *Study Population*

There were 4,233 treatment cards, registered between 1.4.86 and 31.3.88. Cross indexing and identification done during house visits showed that several patients had more than one card, some as many as five. There were 799 such duplicate cards and seventy seven cards of out-of-the-district cases. This left 3,357 newly registered patients from North Arcot district for study and analysis. Of these, 2,305 had been given SCC and 1052 one of the four traditional regimens, giving an acceptance rate of 60% for SCC regimens.

Chart 1 gives the census status of these patients, during the house visits, and the coverage for sputum collection. It is seen that addresses were inadequate in 14%; 10% had migrated and could not be traced and 22% had died. The remaining 1,830 (54%) patients could be contacted in their homes and sputum could be collected from 1,785 (97%). In this manner, the status of 2,512 (75%) out 3,357 patients could be known. These coverages are high and, thus, this paper represents the status of all the patients in the district. Table 2 shows the census status of the 2,305 patients on SCC and 1,052 on traditional regimens separately according to the time of contact in months after the start of treatment.

2. *Treatment Completion*

Out of 2,305 patients who were started on short course regimens, 43% had completed 80% or more of treatment. Forty one percent completed it within the stipulated period of 8 months allowed to complete the treatment. Forty three percent had taken less than 50% of

Chart 1. *Study Population*

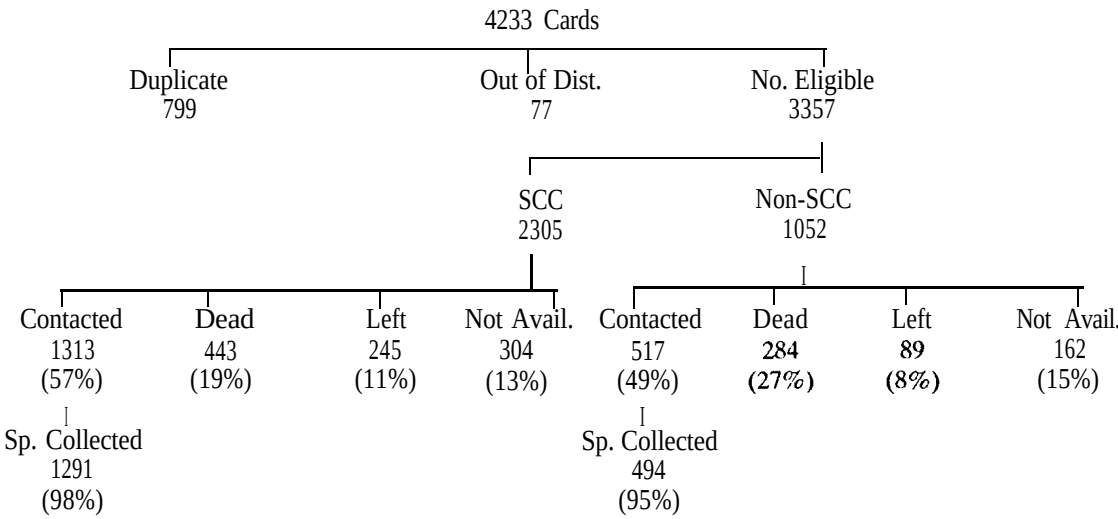

Table 2. *Distribution of patients according to time of contact from start of treatment*

Time of contact (Months)	No. eligible	No. dead	No. available	No. not available
		Short course regimen		
< 9	298	38	189	71
9-11	235	34	143	58
12-17	615	110	368	137
18-23	580	135	295	150
24+	577	126	318	133
Total	2305 (100%)	443 (19%)	1313 (57%)	549 (24%)
		Traditional regimen		
< 9	46	8	28	10
9-11	132	29	75	28
12-17	232	57	115	60
18-23	239	75	124	40
24+	403	115	175	113
Total	1052 (100%)	284 (27%)	517 (49%)	251 (24%)

Table 3. *Duration of treatment related to drug consumption /collection*

Regimen	Duration of treatment (months)	Number of patients according to percentage drugs consumed			
		< 50	50-79	> 80	Total
SCC (52 Doses)	2	642			642
	2-3	266	65		331
	4-5	64	146	164	374
	6-8	14	89	789	892
	9+	7	16	43	66
	Total	993 (43%)	316 (13%)	996 (43%)	2305 (100%)
Traditional (12 Collections)	3	442	2		444
	3-4	70	4		74
	5-8	22	98	4	124
	9-11		35	41	76
	12-14	1	7	94	102
	15-17			113	113
	18+	1	4	114	119
	Total	536 (51%)	150 (14%)	366 (35%)	1052 (100%)

treatment. Of the 1052 patients on traditional chemotherapy, 35%had taken 80% or more of chemotherapy. However, 21 % had taken longer than the specified period of 15 months allowed for the purpose. Fifty one percent took less than 50% of treatment (Table 3).

No comparisons are made in this presentation between short course and traditional regimens as we are primarily interested in the status of all the patients in the district taken together for anti-tubercular treatment under programme conditions.

3. *Mortality*

The overall mortality was 28% (Table 4). The mortality in those who had taken less than 50% of chcmothcrapy was 3-5 times higher than in those who had taken 80% or more of chemotherapy, and this is seen in all age groups.

4. *Bacteriological Status*

Thirty one percent of all patients who had been started on anti-tuberculosis chemotherapy were found to be bacteriologically positive at the time of our visit, which ranged between 6 months to 36 months after the start of treatment (Table 5). Of those who had completed 80% of treatment, 22% were positive, and of those who had taken only 50% or less, 42% were positive. It is to be noted that even among those who had taken only 50% or less treatment, 58% were found to be negative. There was not much difference between SCC regimen and the traditional regimens.

5. *Resistance to Anti-TB Drugs*

Out of 1,783 patients in whom culture results were available, 560 (31%) were found to be positive. Of these, 145 (20%) were resistant to Streptomycin; 365 (65%) were resistant to INH

Table 4. *Mortality according to amount of drugs consumed in respect of age and sex in persons contacted*

Age group (years)	Sex	Number of patients by percentage of drugs consumed							
		< 50%		50-79%		> 80%		Total	
		No. Exam.	No. Dead	No. Exam.	No. Dead	No. Exam.	No. Dead	No. Exam.	No. Dead
upto 15	M	2		2		3		7	-
	F	5	2	-		7	I	12	3
	B	7	2	2		10	1	19	3
15-24	M	69	23	30	5	100	S	199	33
	F	53	19	16	2	65	5	134	26
	B	122	42 (34)	46	7(15)	165	10 (6)	333	59 (18)
25-44	M	360	159	117	21	337	28	814	208
	F	127	55	41	13	168	10	336	78
	B	487	214 (44)	158	34 (22)	505	38 (8)	1150	286 (25)
45-64	M	408	228	112	32	308	39	828	299
	F	50	24	15	6	59	6	124	36
	B	458	252 (55)	127	38 (30)	367	45 (12)	952	335 (35)
65+	M	39	25	13	7	46	10	98	42
	F	2	2	1		2		5	2
	B	41	27 (66)	14	7 (-)	48	10 (21)	103	44 (33)
Total	M	878	435	274	65	704	82	1946	582
	F	237	102	73	21	301	22	611	145
	B	1115	537 (48)	347	86 (25)	1095	104 (10)	2557	727 (28)

Figures within brackets are percentages

Table 5. *Bacteriological status according to the amount of drugs consumed and time of contact after start of treatment*

Time of contact	Number of patients by percentage of drugs consumed							
	< 50		(50-79)		> 80		Total	
(months)	No. Exam.	No. Pos.	No. Exam.	No. Pos.	No. Exam.	No. Pos.	No. Exam.	No. Pos.
				SCC Regimen				
upto 9	74	37	31	13	84	22	189	72
9-14	119	45	52	17	154	25	325	87
15-17	75	32	34	15	73	13	182	60
18-23	93	41	46	17	151	30	290	88
24+	99	42	45	10	159	33	303	85
Total	460	197 (42%)	208	72 (35%)	621	123 (20%)	1289	392 (30%)
				Traditional Regimen				
up to 12	32	12	14	7	47	8	93	34
12-14	26	13	5	1	32	5	63	19
15-17	15	4	4	1	29	6	48	11
18-23	48	17	17	9	53	21	118	47
24+	75	29	7	2	90	26	172	57
Total	196	82 (42%)	47	30 (43%)	251	66 (26%)	494	168 (34%)
Both	656	279 (42%)	255	92 (36%)	872	189 (22%)	1783	560 (31%)

Table 6. *Drug resistance status according to the amount of drugs consumed under SCC and traditional regimens*

Percent drug consumed		Resistant to					
		S		H		R	
	No. examined	No.	%	No.	%	No.	%
				SCC Regimen			
≤ 50	197	36	18	97	49	20	10
50-79	72	14	19	45	62	8	11
≥ 80	123	32	26	99	80	19	15
Total	392	82	21	241	61	47	12
				Traditional Regimen			
≤ 50	82	22	27	50	61	11	13
50-79	20	9	45	15	75	2	10
> 80	66	32	48	59	89	7	11
Total	168	63	38	124	74	20	12
Both	560	145	26	365	65	67	12

and 67 (12%) were resistant to Rifampicin (Table 6).

INH resistance was significantly higher in those who had been put on traditional regimens. Rifampicin resistance was seen even in those who had not received short course treatment. This probably means that patients either concealed history of previous treatment or that they received Rifampicin outside the programme, without being aware of it.