Retrospective Analysis of TB Patients Put on Category-II Under RNTCP at DOTS Centre, BJMC, Ahmedabad.

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ABSTRACT India has approximately two to three million people infected Tuberculosis. This public health problem is the world's largest tuberculosis epidemic.[1] India bears a disproportionately large burden of the world's tuberculosis rates, as it resides to be the biggest health problem in India. It remains one of the largest on India's health and wellness scale. India is the highest TB burden country with World Health Organisation (WHO) statistics for 2011 giving an estimated incidence figure of 2.2 million cases of TB for India out of a global incidence of 8.7 million cases.[2] Compared to Canada, there are about 1,600 new cases of TB every year,[3] which does not largely sum up, even closely, to the amount India suffers through. Citing studies of TB-drug sales, the government now suggests the total went from being 2.2 million to 2.6 million people nationwide.

Tuberculosis (TB) is an infectious disease caused by Mycobacterium Tuberculosis bacteria. It spreads through air when a person suffering from tuberculosis cough, sneeze or spit. TB remains to be major public health problem in India. TB control efforts are initiated countrywide since 1962 with inception of National TB Control Programme. The programme was reviewed and revised strategy was pilot testedin 1993. The Revised National TB Control Programme (RNTCP) was launched in 1997 with implementation of Directly Observed Treatment, Short Course Strategy. The DOTS strategy is based on five components:

- Political and administrative commitment
- Good quality diagnosis, primarily by sputum smear microscopy
- Uninterrupted supply of quality drugs
- Directly observed treatment (DOT)
- Systematic monitoring and accountability

Goals and Objectives of RNTCP

The goal of RNTCP is to decrease the mortality and morbidity due to tuberculosis and cut down the chain of transmission of infection until TB ceases to be a public health problem.

The goal is achieved through the following objectives:

To achieve and maintain:

- Cure rate of at least 85% among newly detected smear-positive (infectious) pulmonary tuberculosis cases; and
- Case detection of at least 70% of the expected new smear positive PTB cases in a community.

The state is achieving twin objectives of RNTCP since 2006. The current focus is on ensuring universal access to quality assured TB diagnosis and treatment services under the programme.

AIM :-
To find out the Success rate of Cat-II and its effectiveness among Treatment Failure, Treatment after default, Relapse and Others groups of patients.

Methodology :-
All adult patients from age group of 18-70 years are included in the study. The data was collected form DOTS centre, BJMC, Ahmedabad form the year 1999 to 2002. They were from different groups : Sputum smear-positive Treatment Failure (Type-A), Sputum smear-positive Relapse (Type-B), Sputum smear-positive Treatment After Default (Type-C), Others (Type-D). Thes regimen selected was DOTS Cat II Treatment. IP [2(SHERZ)$_3$ 1(HERZ)$_3$] , CP [5(HER)$_3$].

Results :-

After the completion of treatment the outcome was studied in six different groups. 1. Cured 2. Treatment Completed 3. Treatment Failure 4. Defaulter 5. Death and 6. Transferred out.

Study of Total 529 patients done. Out of 529 patients 63.5% patients are form Treatment After Default group (Type-C). Overall cure rate of all 4 years is 41.0% and Treatment completion rate is 12.8%, Treatment failure rate is only 18.3% and Defaulter rate is 19.8%.

Death rate is only 7.1%, and it is highest among others (Type-D) followed by Treatment after default (Type-C) group

Conclusion :-
Success Rate of Category-II is 53.8%.

Success Rate is very good among Others (Type-D) and Relapse (Type-B) group.

Those patient's who failed Category-I/III, chances of success by Category-II are very less because they are mostly drug resistant cases.

Those patient's who are defaulter they have tendency to default and increases the defaulter rate and also death rate.

MATERIALS AND METHODS
■ **Eligibility for the patients to put on Category-II are:**
1. Sputum smear-positive Treatment Failure (Type-A)
2. Sputum smear-positive Relapse (Type-B)
3. Sputum smear-positive Treatment After Default (Type-C)
4. Others (Type-D)

■ **Age Group:**
18-70 yrs.
Male 389 (73.5%)
Female 140 (26.5%)
Total 529

■ **Regimen:**
IP [2(SHERZ)$_3$ 1(HERZ)$_3$]
CP [5(HER)$_3$]

TREATMENT OUTCOME GROUPS
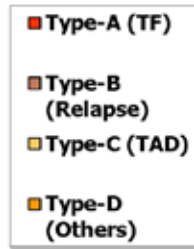After a completion of full course of treatment outcomes were studied in six different groups :

1. **CURED:** Initially smear-positive patient who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at completion of treatment.
2. **TREATMENT COMPLETED:** Sputum smear-positive case who has completed treatment, with negative smear at the end of the initial phase but none at the end of treatment. *OR* Sputum smear-negative TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment. *OR* Extra-pulmonary TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.
3. **TREATMENT FAILURE:** Smear-positive case who is smear-positive at 5 months or more after starting treatment. Also, a patient who has initially smear-negative but who became smear-positive during treatment.
4. **DEFAULTER:** A patient who, at any time after registration, has not taken anti-TB drugs for 2 months or more consecutively.
5. **DEATH:** Patient who died during treatment, regardless of cause.
6. **TRANSFERRED OUT:** A patient who has been transferred to another tuberculosis unit/district and his/her treatment results are not known.

OBSERVATION
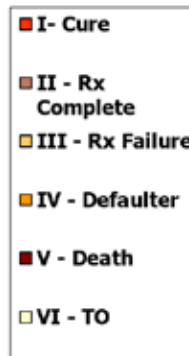1. **Types of cases put on Category-II**

YEAR	Treatment Failure (Type-A)	Relapse (Type-B)	Treatment After Default (Type-C)	Others (Type-D)	TOTAL
1999	7(10.1%)	3(4.3%)	57(82.6%)	2(2.8%)	69
2000	26(14.7%)	24(13.6%)	117(66.4%)	9(5.1%)	176
2001	20(13.4%)	18(12.0%)	87(58.3%)	24(16.1%)	149
2002	15(11.1%)	20(14.8%)	75(55.5%)	25(18.5%)	135
TOTAL	68(12.2%)	65(12.2%)	336(63.5%)	60(11.3%)	529

- Type-A (TF) — 12.80%
- Type-B (Relapse) — 12.20%
- Type-C (TAD) — 63.50%
- Type-D (Others) — 11.30%

1. OUTCOME OF CASES PUT ON CATEGORY-II

YEAR	(I) CURE	(II) Treatment Complete	(III) Treatment Failure	(IV) Defaulter	(V) Death	(VI) Transfer Out	TOTAL
1999	28(40.5%)	12(17.3%)	9(13.0%)	16(23.1%)	4(5.7%)	0	69
2000	76(43.1%)	16(9.0%)	32(18.1%)	38(21.5%)	13(7.3%)	1	176
2001	48(32.2%)	20(13.4%)	31(20.8%)	34(22.8%)	16(10.7%)	0	149
2002	65(48.1%)	20(14.0%)	25(18.5%)	17(12.5%)	5(3.7%)	3	135
TOTAL	217(41.0%)	68(12.8%)	105(19.8%)	105(19.8%)	38(7.1%)	4(0.7%)	529

- I - Cure — 41.00%
- II - Rx Complete — 12.80%
- III - Rx Failure — 18.30%
- IV - Defaulter — 19.80%
- V - Death — 7.10%
- VI - TO — 0.70%

DETAIL ANALYSIS OF EVERY OUTCOME

| OUTCOME	1999 (69) A	B	C	D	2000 (176) A	B	C	D	2001 (149) A	B	C	D	2002 (135) A	B	C	D	TOTAL
I (CURE)	3	1	22	2	7	14	54	1	6	7	34	1	6	15	44	0	217 (41.0%)
II (Rx Complete)	1	1	10	0	1	1	12	2	0	2	1	17	0	0	3	17	68 (12.8%)
III (Rx Failure)	1	0	8	0	8	3	21	0	4	4	21	2	7	5	12	1	97 (18.3%)
IV (Defaulter)	2	0	14	0	9	6	22	1	7	3	21	3	2	0	11	4	105 (19.8%)
V (Death)	0	1	3	0	1	0	11	1	3	2	9	2	0	0	3	2	38(7.1%)
VI (TO)	0	0	0	0	0	0	1	0	0	0	0	0	0	20	3	0	4(0.7%)
TOTAL	7	3	57	2	26	24	121	5	20	18	86	15	15		76	24	529

3. SUCCESS RATE
[CURE+TREATMENT COMPLETION]

YEAR	TREATMENT FAILURE (TYPE-A)	RELAPSE (TYPE-B)	TREATMENT AFTER DEFAULT (TYPE-C)	OTHERS (TYPE-D)	TOTAL
1999	4	2	32	2	40(57.9%)
2000	8	15	66	3	92(52.2%)
2001	6	9	35	18	68(45.6%)
2002	6	15	47	17	85(62.9%)
TOTAL	24 (35.2%)	41(63.0%)	180(54.5%)	40 (66.6%)	285(53.8%)

4. TREATMENT FAILURE RATE

YEAR	TREAT-MENT FAILURE (TYPE-A)	RELAPSE (TYPE-B)	TREAT-MENT AFTER DEFAULT (TYPE-C)	OTHERS (TYPE-D)	TOTAL
1999	1	0	8	0	9(13.0%)
2000	8	3	21	0	32(18.1%)
2001	4	4	12	2	31(20.8%)
2002	7	5	12	1	25(18.5%)
TOTAL	20(29.4%)	12(18.4%)	62(18.4%)	3(5.0%)	97(18.3%)

Type-A (TF)
Type-B (Rel)
Type-C (TAD)
Type-D (Others)
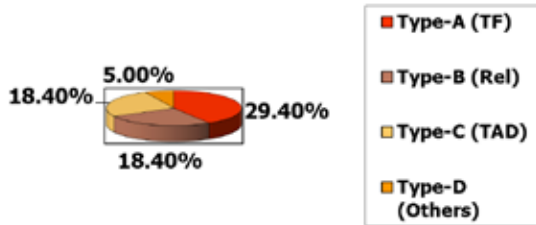
5. DEFAULTER RATE

YEAR	TREAT-MENT FAILURE (TYPE-A)	RELAPSE (TYPE-B)	TREAT-MENT AFTER DEFAULT (TYPE-C)	OTHERS (TYPE-D)	TOTAL
1999	2	0	14	0	16(23.1%)
2000	9	6	22	1	38(21.5%)
2001	7	3	21	3	34(22.8%)
2002	2	0	11	4	17(12.5%)
TOTAL	20(29.4%)	9(13.8%)	68(20.2%)	8(13.3%)	105(19.8%)

6. DEATH RATE

YEAR	TREAT-MENT FAILURE (TYPE-A)	RELAPSE (TYPE-B)	TREAT-MENT AFTER DEFAULT (TYPE-C)	OTHERS (TYPE-D)	TOTAL
1999	0	1	3	0	4(5.7%)
2000	1	0	11	1	13(7.3%)
2001	3	2	9	2	16(10.7%)
2002	0	0	3	2	5(3.7%)
TOTAL	4(5.8%)	3(4.6%)	26(7.7%)	5(8.3%)	38(7.1%)

DISCUSSION

- Out of 529 patients 63.5% patients are form Treatment After Default group (Type-C). Other three groups are very less.
- Overall cure rate of all 4 years is 41.0% and Treatment completion rate is 12.8%, Treatment failure rate is only 18.3% and Defaulter rate is 19.8%.
- Treatment failure rate is more common among Treatment failure group (Type-A). These suggest that those patient's who failed Category-I/III chances of success by Category-II are very less.
- Out of 19.8% of Defaulter cases patient's from Treatment failure (Type-A) and from Treatment After Default (Type-C) are more. This shows that patient's who are defaulter previously they have tendency to default.
- Death rate is only 7.1%, and it is highest among others (Type-D) followed by Treatment after default (Type-C) group. This suggest that Defaulter patient's increasing the ratio of treatment failure and death rate.

CONCLUSION

- Success Rate of Category-II is 53.8%.
- Success Rate is very good among Others (Type-D) and Relapse (Type-B) group.
- Those patient's who failed Category-I/III, chances of success by Category-II are very less because they are mostly drug resistant cases.
- Those patient's who are defaulter they have tendency to default and increases the defaulter rate and also death rate.

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