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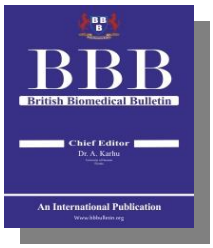

Original Article

Clinical Evsaluation of Short Term Regieme in Management of Pulmonary Kochs

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A R T I C L E I N F O

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A B S T R A C T

Declining nutritional and economic status poses increased threat of Koch's lesion even among middle class family. Considering the cost of Anti tuberculosis treatment, high disease endemicity due to emergence of resistant strain of mycobacterium tuberculosis and hepatotoxicity of currently used Rifampicin, Pyrizinamide and Ethambutol, A safe drug combination is a need of the time. Hence a drug regime constituting Levofloxacin 500mg and Isoniazide 300mg was evaluated in pulmonary tuberculosis .

Objective: To short out safe potent short term anti tuberculosis regime, improved treatment for drug resistant cases and provide effective schedule to check endemicity and insure natural lung repair to secure normal lung's vitality.

Material method: 156 clinicopathologically and radiologically established cases of Pulmonary tuberculosis were put on the trial regime, with high protein diet. Each patients were duly evaluated for pre and post vital capacity of lung, hematological, hepatic and renal status.

Result: reveals early sputum conversion, resolution or alleviation of presenting features, improvement in appetite, weight gain with limitation of sputum infectivity and disease communicability in 60±5 days, weight gain of6±2kg ,non recurrence or relapse of the disease in 1 yr post therapy follow up, improved lung vitality , body physique and 100% drug compliance with complete safety profile(Hemato, hepato renal function)

Conclusion: This regime show complete relief of clinical presentation with clinicopathological and radiological cure in all the cases without any adversity or relapse.

Introduction

Tuberculosis is a widely spreading infectious disease prevalent in India[1-3] As per W.H.O India contributes 1/5th of the worldwide tuberculosis every year i.e.-9.4 million Or 1.98million cases every year.3.3 millions people suffers from one or other form of tuberculosis and annually 2,76,000 people die every year due to tuberculosis[4,5] . As per National TB control program incidence is 176/lakh, prevalence 230/lakh and mortality is 22/ lakh population[6]. In spite of W.H.O supported RNTCP, effective control remains a continuing major set back of Indian health scenario. Tuberculosis is no less than a silent contagious disease having devastating impact on life[7,8].

As per the RNTCP schedule and its objective patients never gets cure of the diseases but only gets sputum conversion and never ensure achievement of normal respiratory function due to healing with extreme fibrosis leading to reduction in functioning lung parenchyma and majority patient presents with recurrent haemoptysis, breathlessness or respiratory distress Or disease dissemination resulting in systemic tuberculosis[9,10].

In RNTCP drug administration without improved nutrition fails to provide natural healing of the pulmonary parenchyma, resulting in decreased gaseous exchange in pulmonary bed resulting in altered metabolic function and failure to gain body weight. The ancient parameter of weight gain as an index of prognosis in tuberculosis management, still remain significant.

Considering the principle of Koch's management i.e.-prescription of a potent antimicrobial agent to check its growth promptly, agents to promote and ensure natural parenchyma repair, agents to reduce drug's toxic effect. Antimicrobial agents should be such that sputum conversion must be firm and expectoration should not contains any active tuberculosis bacilli to check endemicity[11,12].

Considering the fact the therapeutic regime been evaluated at RA. Hospital & Research Centre Warisaliganj (Nawada) Bihar, India.

Material & Methods

Material

Patients attending medical OPD of RA. Hospital & Research Centre, Warisaliganj (Nawada) with complaints of –

- Evening rise of temperature ^{o}C
- Chronic cough since last 2 months
- Loss of appetite,
- Progressive debility
- Pain in the chest

Were thoroughly interrogated regarding their clinical presentation, treatment taken and their response. Clinically examined and investigated, Sputum for AFB, Blood for ESR, CBC and basic parameters, X-ray chest to establish the diagnosis and asses the pulmonary parenchyma damage. Among them 156 clinico pathologically and radiologically confirmed new cases of pulmonary tuberculosis without any other associated disease attending RA. Hospital & Research Centre were selected, duly interrogated, and investigated.

Patients were assessed for basic status of weight, hematological, hepatic and renal parameters to assess the clinical efficacy and safety profile of the therapeutic regime. Patients/parent of the patients were duly explained regarding the proposed regime, its schedule and any known drug adversity or precautions.

Methods

Selected patients after due awareness regarding the protocol were advised-

- High protein diet (Milk or milk products)

- New adult cases of pulmonary tuberculosis were give two drug therapy i.e.- Levofloxacin 500mg and Isoniazide 300mg orally daily, and inj Neohepatix 1 amp intramuscular every week
- Patients were assessed weekly for their clinical presentation i.e.- bout of cough, amount of expectoration, status of appetite, body weight, hemato, hepato-renal and pulmonary functions.
- In addition sputum was evaluated every week for sputum conversion, x ray chest repeated after 2 months of therapy.
- Patient was followed up for next 6 months on monthly interval and x-ray was repeated when patient shows complete clinicopathological cure.

Observation

Selected patients were of age group 20-60 yrs and 14% were of age >55 yrs and 23% were of age<30 yrs with male: female composition 113:43 i.e.73% male and 27% female.(T-I, and pie diagram)

Common presentation was fever, general debility and loss of appetite, while cough expectoration, and pain in chest was second common presentation, 18 cases presented with frank hemoptysis. (T- II)

Base line hemato, hepato-renal status shows Hemoglobin <10gm in 41%,presence of albumin in 5% cases only, while sputum of all cases were positive for AFB, radiological examination reveals more involvement in right t apex, ESR >100 in 69% cases, Lymphocytosis (.46%) in all , normoglycemic, BCG diagnostic (induration >6mm) in 96% cases (T- III and T- IV)

2 months post therapy follow up reveals sputum conversion in all, radiological resolution of lesion in 67% and 1% female while weight gain in 96%(77.4% male and 25% female),rise in hemoglobin in 94.6% ,altered hepatic function in 1%,improved appetite in 96% and renal function remains unchanged.(T- V)

Discussion

Incidence of pulmonary tuberculosis is on rise in spite of WHO intervention, National Tuberculosis Control Program and launch and execution of RNTCP, as during treatment of tuberculosis patient clinician consider sputum conversion and radiological resolution of the lesion as prime index of assessment, but it is observed that the crude index of self reliance i.e.- Progressive body weight gain remains still significant . Poor nutrition and nutritionally deprived diet poses a threat to natural repair of diseased lung parenchyma which lately present as decreased lung vital function and poor oxygenation leads to poor metabolism and weight gain[14,15].

In addition when ever any case of old treated Pulmonary Tuberculosis presents with cough Or haemoptysis clinician straight way prescribe Anti tuberculosis treatment without assessing the previous anti tuberculosis therapy and its outcome, present state of infection, sensitivity of drug to infective pathogen, present lung vital capacity, which again leads to fibrotic lesions of lung parenchyma with progressively declining lungs vital function and patient present with respiratory distress.

Achievement of complete recovery and sputum conversion with maintained vital capacity of lung and improved physique in all the cases are primarily due to–

- Non existent drug resistance and Levofloxacin[16,17] being a drug acting on Mycobacterial nuclei by its action on DNA gyrase, Topo isomerase I and Topo isomerase II having high volume distribution help in early sputum negativity (40±5 days) and weight gain of approximately 6.8±1.2 Kg in 60 days

of therapy with complete drug compliance and alleviation of presenting features.

- Early sputum conversion promote natural healing of lung parenchyma, in addition limits expectoration of active infective mycobacterium tuberculosis bacilli, thus also limit disease endimicity.
- In addition supportive bacteriostatic drug Isoniazide provides a protection from any re infection[3]
- Inj. Neohepatix (a microsomal hepatic enzyme concentrate) improves hepatic function and metabolism yielding a better physique[13]
- These short term treated koch's patients were followed up for complete 1 year for any recurrence of chest infection, or debility and revealed no such incidence.

Conclusion

High protein food supplement milk with single daily therapeutic dose of Levofloxacin and Isoniazide with Hepatic microtonal enzyme concentrate supplement for 2 months achieved complete reversal of clinical presentation with clinic-pathological and radiological cure in all cases of pulmonary koch's.

This observation requires extensive large scale study for the benefit of mass

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Table 1. Age and sex wise distribution of patients

Age group	Number of patients		
(in yrs)	MALE	FEMALE	TOTAL
20-25	12	03	15
25-30	15	08	23
30-35	09	03	12
35-40	17	06	23
40-45	20	08	28
45-50	17	03	20
50-55	10	03	13
55-60	13	09	22
Total	113	43	156

Table 2. Distribution of patients as per clinical presentation

Clinical presentation	Number of patients
Fever (Evening rise of temperature)	156
Cough with expectoration	138
Loss of appetite	150
General debility	156
Hemoptysis	118
Pain in chest	136

Table 3. Distribution of patients as per basic hematological, hepatic and renal parameters

Parameters	Number of patients		
	MALE	FEMALE	TOTAL
Hematological : Hemoglobin :			
>10gm	90	09	99
<10gm	23	34	57
Hepatic: Serum bilirubin:			
>1mg%	-	-	-
<1mg%	113	43	156
SGOT:			
>35 IU	-	-	-
<35 IU	113	43	156
SGPT:			
>35IU	-	-	-
<35IU	113	43	156
Alkaline phosphatase:			
>140 IU/L	-	-	-
<140 IU/L	113	43	156
Renal: Blood urea:			
>20mg/dl	-	-	-
<20mg/dl	113	43	156
Serum creatinine:			
>1.5mg%	-	-	-
<1.5mg%	113	43	156
Urine Albumin:			
Present	09	-	09
Absent	104	43	156

Table 4. Distribution of patients as per clinical status

Parameters of patients	Number
Sputum positive for AFB	156
Radiological appearance:	
Rt apex involvement	148
Rt upper and middle lobe	06
Left upper	02
Hematological status: ESR:	
>100 mm	139
80-100mm	16
70-80mm	01
Lymphocytosis	156
(.46%) Hemoglobin :	
<10gm	123
>10gm	33
BCG diagnostic:	
Induration >6mm	154

Table 5. Status of patients after 2 months of therapy

Particulars	Number of patients		
	MALE	FEMALE	TOTAL
Sputum for AFB:			
Positive	None	None	
Negative	113	43	156
Radiological:			
Lesion resolved completely	104	03	107
Persistence of lesion	09	40	49
Weight gain:	110	40	150
Weight loss:	03	03	06
Hemoglobin:			
Raised	110	40	150
Unchanged	03	03	06
Decreased	- -		-
Hepatic function:			
Suppressed	03	03	06
Improved	110	40	150
Appetite:			
Improved	110	40	150
Unchanged	03	03	06
Decreased	- -		-
Renal function:			
Altered	-	-	-
Unchanged	113	43	156
Compliance	113	43	156
Drug withdrawal	None	None	None