

EDITORIAL

SC Abolishes Thrice Weekly Dose; Restores Daily Dose Protocol in TB Across India

Raman Kakar

Email id: raman24march@yahoo.com

ABSTRACT

On 23 January 2017, the Supreme Court of India delivered a historic judgement on DOTS (Directly Observed Treatment Short course), that will affect the fate of ailing millions – 27% of global tuberculosis patients. Government of India shall switch over to daily dose protocol as soon as possible. No sick Indian can be placed on ‘Thrice weekly dose’ after 9 months from today.

Keywords: TB, DOTS, RNTCP, Tuberculosis, Thrice weekly dose, Daily dose, Supreme Court

HISTORY

A Writ Petition (Civil) No. 604 of 2016 was filed by a doctor in the Supreme Court of India challenging ‘the way tuberculosis (TB) is being treated’. It sought to abolish government’s protocol of administering ‘3 doses of medicines per week’ and to replace that with ‘daily dose’ regimen under DOTS.

Petitioner, Dr. Raman Kakar (www.tbfreeworld.org), who headed one of the government’s 3,000 odd sub-district TB units in India, claims that the current DOTS model is unscientific, ineffective and harmful. Giving only three doses (instead of seven) per week no doubt reduces cost (to 43%), but it also means drastic reduction of drug intake, which truncates therapy and weakens it. Even a (Category II) patient in India ends up getting only 24 injections (of streptomycin) in 2 months, whereas in other countries (using daily dose), such a patient gets 60 injections!

As a result, Indians are not getting proper, long-lasting recovery. Too many treated patients return sick for yet another course of treatment. India’s relapse (and recurrence) rates are quite high (10%) compared with about 3% internationally.

Kakar and his dedicated team of TB workers serving under Revised National TB Control Programme at district Faridabad (Haryana) have been conducting exhaustive research for over 6 years^[1]. Long-term fate of 36,785 patients, registered under thrice-weekly era (2000–2016), was scrutinised. Of them, 4,675 (12.7%) were found re-registered for a second innings of medication (enrolled twice). Curing them a second time is much harder. The team came across several patients who had already undergone four, five or six protracted courses of government’s thrice weekly therapy but were still sick (or dead). Daily dose regimen is traditional, time tested and more widely accepted. A total of 20 (out of 22) high TB burden countries practise daily-dosing schedule^[2]. There is insufficient evidence to compare intermittent with daily regimen, concludes Cochrane^[3]. Review in Thorax justifies daily dosing, particularly in initial phase^[4]. India-specific review by Azhar^[5] stated ‘Relapse rate is high (almost 10%) in India’. In South India, of 503 patients cured, 9.5% relapsed within 6 months^[6]. Kakar has quoted several other scientific studies in his 504-page petition.

Medical Officer (Ex), Tuberculosis Control, Revised National TB Control Program (RNTCP) of India, District TB Center, Faridabad, Haryana, India

Petition further warns that rather than eradicating TB, our billion-dollar programme may be doing the very opposite – generating lethal, drug-resistant strains (through high recurrence) and that too on an industrial scale, ominous for mankind. We seem to be headed back to pre-antibiotic era of our grandparents when TB used to be incurable.

It is a pity that someone has had to resort to legal recourse for such a clear-cut scientific topic and which underscores total government apathy.

In their reply (counter affidavit), government, while denying most of the ‘averments’, has agreed to switch over to daily dose protocol in a phased manner over 2 years, but Kakar urges them to do so urgently, on war footing – before 2 October 2017; modern India does possess the wherewithal.

Mr. Maninder Singh, additional solicitor general, argued that government’s current stock of (thrice weekly) drugs worth Rs. 117 crores will be a wastage. Kakar says ‘No. Just remove one tablet of H and half tablet of E, and the “present IP strip” becomes a “daily IP dose” – with R450, H300, E900, Z1500 mg’. Reconstituted thus, entire buffer stock will be used up as daily doses - an acceptable compromise, with no national losses. Besides, human life transcends monetary considerations.

Government boasts that TB is declining, which is disputed by recent reports that India’s morbidity and mortality figures for 2015 have been revised upwards by Global TB Report, bursting the Indian bubble – a national disgrace.

Kakar vehemently opposes the government’s unsubstantiated claims that 132 countries globally had similarly adopted thrice weekly regimen. He claims that India is one of the few exceptions to experiment with low-cost, thrice weekly protocol at such a large scale – a historic blunder, for which accountability ought to be fixed.

World Health Organisation WHO is India’s technical advisor having a huge presence in India; 87 influential WHO consultants busily conduct money-drenched

surveys. So, WHO too owes an apology to the public of India for 20 years of malpractice. Kakar strongly feels that the family of registered dead and survivors (who avoidably suffered recurrences) ought to be awarded monthly pension as compensation.

Government admitted in their reply that ‘..., WHO in 2007, and again in 2010, advised daily treatment as the preferred drug regimen ...’? So, he asked, ‘why wait? How many more deaths/recurrences/drug-resistant cases before we act’?

Kakar didn’t incur any expenditure on his PIL (public interest litigation), except on stationary or metro rail fare. He didn’t engage any advocates and argued himself. Supreme Court of India is a magnificent institution; the three-judge bench headed by the Hon’ble Chief Justice adjudicated at a lightning speed – five hearings in 4 months.

REFERENCES

- [1] Kakar R. Fully intermittent, thrice-weekly dose of anti-tuberculosis drugs; their efficacy under routine program conditions of India. *J Health Sci* 2016;4:15–25. DOI: 10.17265/2328-7136/2016.01.003.
- [2] Wells WA, Konduri N, Chen C, Lee D, Ignatius HR, Gardiner E, et al. Implications of the current tuberculosis treatment landscape for future regimen change. *Int J Tuberc Lung Dis* 2011;15(6):746–53.
- [3] Mwandumba HC, Squire SB. Fully intermittent dosing with drugs for treating tuberculosis in adults. *Cochrane Database Syst Rev* 2001;4. Art. No. CD000970.
- [4] Chang KC, Leung CC, Grosset J, Yew WW. Review; treatment of tuberculosis and optimal dosing schedules. *Thorax* 2011;66(11):997–1007. DOI: 10.1136/thx.2010.148585.
- [5] Azhar GS. DOTS for TB relapse in India: a systematic review. *Lung India* 2012;29:147–53.
- [6] Thomas A, Gopi PG, Santha T, Chandrasekaran V, Subramani R, Selvakumar N, Eusuff SI, Sadacharam K, Narayanan PR. Predictors of relapse among pulmonary tuberculosis patients treated in a DOTS program in south India. *Int J Tuberc Lung Dis* 2005;9(5):556–61.

Received: 13.02.2017

Accepted: 25.02.2017