PERSONALISED THERAPY VS. FIXED DURATION THERAPY

Editor,

The therapeutic aspect of medical sciences cannot be equated to mathematics and cannot be standardized. The phrase itself 'Fix Duration Therapy' sounds unscientific and naïve. The 'ars therapeutica' is a complex art which needs time to be mastered and has to take into account many factors:

1 the objective therapeutic value of a given drug;
2 the absorption, metabolism, pharmacokinetics of the drug;
3 the personality and general conditions of the patients; and
4 the personality of the attending medical officer.

Too many variables for any standardization to be significant and practical.

As a matter of fact every physician has his/her own therapeutic regimen for any given disease. In the management of common ailments a physician will take the textbook's prescriptions as a broad guideline, filter them through his/her experience and finally adapt them to the patient's need, age, personality and general conditions.

Where communicable diseases are concerned—which pose a public health problem–the possibility of a conflict between the public health authorities and the physicians is not a remote hypothesis. Let us consider the case of leprosy.

The public health officer is, usually, a non-practising physician, therefore he/she thinks and behaves like a bureaucrat, whose main concern are statistics and the cost of therapeutics, that is the lowest cost! On the other hand a practising physician does resent the fact that somebody, with limited or no clinical knowledge at all, should dictate him.

The WHO guidelines of MDT are, I believe, just guidelines, i.e. that paucibacillary (PB) patients should be treated with *at least 2 drugs for at least 6 months and a multibacillary (MB) with three drugs for at least 2 years.* Unfortunately the bureaucrats read the guidelines with a different mind-frame: 6 months therapy is the *maximum* allowed for a PB patients and if the medical officer, in his judgement, feels that a particular patient requires 3 drugs for a longer period, he is labelled spendthrift or ignorant or both.

On the issue of fixed duration therapy (FDT) the Workshop on Chemotherapy held at Orlando in 1993 stressed two important points:

1, 'Fixed duration regimen may prove to be inadequate in previously untreated LL patients with a high bacterial load ... caution (*should be used*) in the widespread adoption of 2-year fixed duration treatment, and 2, '... many relapses are occurring late and, therefore, five years' post-treatment follow-up appears to be inadequate, 8–10 years being the minimum required.'[1] Yet the Indian Government has adopted FDT. It is possible that behind such decision there are bureaucrats and desk-doctors.

An analysis of all the data published is beyond the scope of this letter; at any rate most of the data so far available are based on small samples or a short follow-up or both. So one can say that FDT is based on insufficient scientific data, it does not respect any of the principles of 'ars therapeutica' mentioned above and it is against the psychology of the patient and of the doctor alike.

Moreover it is *legally questionable*. A few points will give credit to my views:

1 Waters[2] has given a fair evaluation of relapses following various regimens. He says: 'Both from experience with WHO–MDT and from other regimens, a follow-up of 8–10 years appears essential.' So reports based on a shorter period cannot be considered as indicative and/or conclusive.

2 A group of thorough and reliable scientists has found viable *Mycobacterium. Leprae* (30%) in the peripheral nerves of MB patients treated with WHO regimen.[3]

3 The therapeutic regimen is, usually, based on clinical diagnosis and, in some cases, on the bacteriological index. It has been found that there is often a discrepancy between the clinical classification and the nerve biopsy report even when the diagnosis is made by an experienced clinician. Usually the nerve biopsy shows a higher BI then the skin,[4,5] so what appears as a PB is in fact a MB case.

4 Every patient is a different case and we, the clinicians, know too well that patients do not respond in the same way to the same drug: the variations in clinical response and the side effects are unlimited.

5 To my knowledge there is no disease where FDT is advocated. No doubt there are diseases for which 'protocols' have been *suggested by experts*; yet such protocols give a lot of freedom to the attending doctor.

6 As far as India is concerned, collection of statistics and treatment is done, by and large, by para-medical workers (PMWs). Without pointing the finger at anybody, we have to admit that the collection of data is faulty in a large number of cases and the way the treatment is given is not what I would desire for my son. There are good and bad reasons for it. Difficult terrain, mountainous areas and no transport facilities; at times a PMW has to walk a few miles to contact a single patient. The bureaucrats have set some targets like 'three new cases to be detected per month…,' and they want to see nice-looking statistics, in other words they like reports that show a constant decline in new cases, complete cure with the WHO regimen and no-relapses. Understandably a PMW may be tempted to please the 'boss'—after all his/her bread is at stake. It follows, I know it for sure, that: 1, If a PMW finds 12 new cases in his area, he will register only 3 (because this is the target!); and 2, at the end of the prescribed 6 or 24 months of therapy he will cancel the patient from the 'active register'; whether the patient has received only one capsule of rifampicin or 6 or 24 it is immaterial; the point is 'the *statistics* have to be in order and pleasing'.

7 What will happen when, at the end of 6 months, a PB patient thinks that he is not cured? It is very difficult to convince an educated patient that he is cured when the clinical signs are still visible. In the case of illiterate patients it is an impossible task. If the attending doctor tells the patient that he is cured and does not need any further therapy what will happen next is easy to guess. The patient will go to another doctor, who, on clinical evidence, will put the patient on another 6 months therapy. The patient may go to an Ayurveda or homeopathic doctor or even a 'quack', who will prescribe 4–8 drugs (I have seen such prescriptions!).

Eventually the patient will be treated for 2–3 years by various doctors and 'quacks'. So why not let the first doctor keep the patient under therapy for 1 year or so?

8 A doctor is legally responsible for his/her prescriptions. I, as a practising clinician, can and must take responsibility for all my actions. What about a young doctor working in a Governmental set-up? He is told what to prescribe and he has to obey orders or else … Who is legally responsible for complications, relapses, re-activation? So far our patients have been too good to us (and we too lucky). The day will come when a smart patient will take the doctor to court for complications and/or relapse. Who is going to take the blame and face the legal consequences?

In all fairness the directors of all the units (voluntary or governmental) who adopt, and impose, FDT should sign a document wherein they exonerate their doctors from any complications/relapse arising from FDT.

The practical question however is another one: do we need to have FDT?

If one single doctor had to care for ten thousand patients, a standard regimen might be practical though not ideal. But take the case of Bombay; last year there were—as per official statistics[6]—about 4600 active cases and more than 30 doctors engaged in this field. Under these circumstances the only scientific way to go about it is to personalize the treatment.

A personalized treatment is the rule in medical practice. It respects the patient and the doctor too. If you advocate FDT the role of the doctor is reduced to a 'rubber stamp': once the diagnosis is made you do not need doctors any longer but clerks.

FDT is the most frustrating thing for any real clinician who cares for his patients and likes to have a direct rapport with them. As a matter of fact hardly any dermatologist, in Bombay, follows the guidelines of WHO and least of all the FDT. Almost none of them is happy with the clinical results of WHO regimen. You cannot convince a doctor to adopt a therapy which, according to him, is not good enough or sufficient; after all he has to care for his good name too.

My suggestions:

1 Have guidelines, but let the doctors follow their knowledge and experience and take full responsibility for their prescriptions. And if the attending doctor feels that a particular patient needs 3–4 drugs he should be allowed to exercise his judgment.

2 Make it clear that the WHO regimen is the 'minimum' therapy and not the 'maximum'. Even the advocates of FDT admit that of the BI, at inception, is more than +4, a much longer period of treatment may be required.[7]

3 It is my experience extending over 20 years (and many thousands of patients) that when the patient is told about the remote possibility of relapse even the poorest will insist on having as many drugs as necessary and for as long as possible. Unfortunately, given the present trend, hardly anybody takes the trouble of explaining anything to the patients. The patient has to be explained the pros and cons of various regimens.

In conclusion I say that as a responsible doctor I am ready to take advice from my peers and elders but, in the final analysis the type of treatment and the duration is my decision and mine alone. I cannot and will not allow a bureaucrat to dictate to me.

One last work. One day I asked one of those doctor-bureaucrat: 'If your son had a TT type of leprosy, would you give him the WHO regimen?' 'Certainly not!' was the candid and prompt reply and my rejoinder: 'If 6 months therapy is not good for your son how can it be good for a poor man's son?'

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